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DESIGNER DRUGS, 1985

HEARING

BEFORE THE

SUBCOMMITTEE ON CHILDREN,
FAMILY, DRUGS AND ALCOHOLISM

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

INVESTIGATING THE THREAT OF DESIGNER DRUGS AND EFFORTS TO STOP THEM

JULY 25, 1985

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DESIGNER DRUGS, 1985

THURSDAY, JULY 25, 1985

U.S. SENATE,
SUBCOMMITTEE ON CHILDREN, FAMILY,
DRUGS AND ALCOHOLISM,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The subcommittee convened, pursuant to notice, at 10:10 a.m., in room SD-562, Dirksen Senate Office Building, Senator Paula Hawkins (chairman of the subcommittee) presiding.

Present: Senators Hawkins, Grassley, and Dodd.

Also present: Senator Chiles.

OPENING STATEMENT OF SENATOR HAWKINS

Senator HAWKINS. Good morning.

Today, the Subcommittee on Children, Family, Drugs and Alcoholism will investigate the threat of designer drugs and efforts to stop them.

I would like to compliment my Florida colleague, Senator Chiles, on his leadership in the issue of designer drugs. In March of this year, he introduced legislation on designer drugs and chaired an excellent hearing into this matter last week. I have invited him to participate in today's hearing and he has indicated he would attempt to join us. He has another meeting, as we all do, and he will try to join us as this panel commences.

This subcommittee looks forward to Senator Chiles' participation. Senator Dodd has indicated he will be here, Senator Grassley, and other members of the full committee.

Tragically, drug abuse is responsible for lowered national productivity, impaired military preparedness, failed education, increased violent crime, corruption, addiction, and death.

Until today, the sources of the illicit narcotics that cause these devastating societal problems have been foreign poppy, coca, and marijuana fields. We have tried to cut off these sources, to stop drug-producing nations from cultivating and marketing their crops. Now we are confronted with an entirely new problem. Sophisticated chemists are creating synthetic heroin, synthetic cocaine, and numerous other kinds of narcotic analogs in clandestine laboratories, with minimal cost and effort, all over the United States of America. These designer drugs, as they are called, are proving to be even more destructive than their parent plants. They are high-tech killers.

In laboratories, originally on the west coast, but now found all over this country, outlaw chemists are taking $50 worth of materi-

als found in any hardware or pharmaceutical store, and with it, creating 100 million doses of synthetic narcotics.

These drugs bring about the same high, the same addiction, and the same death as natural narcotics, but with much greater potency. Numerous drug abusers in California discovered how potent—over 100 people have died so far in California just from taking designer drugs.

They have also been the cause of a near epidemic of Parkinson's disease on the west coast. One of these drugs, a fentanyl derivative, has been found to be responsible for a large number of Parkinson's disease, an incurable neurodegenerative affliction.

You will be seeing on film later in this hearing just how devastating this disease can be.

The most remarkable aspect of this situation is that until very recently, these substances were legal. Since the laws dealing with narcotics control define illegal drugs by their exact molecular structure, the creators simply have to alter their product slightly, as soon as it has been made illegal by the Drug Enforcement Administration. What has occurred in this new system of narcotics production is that by the time scientists decipher the structure of the chemist's latest product and enforcement agencies take steps to outlaw it, the manufacturer simply redesigns the molecule.

Designer drugs is a whole new class of killers, providing a whole new set of victims. The potential cost to society of this growing national problem is staggering.

This is something on which we all agree—law enforcement officials, treatment authorities, and legislators alike. This growing problem has been called the drug wave of the future, and needs a coordinated effort from all quarters to combat it.

Certain aspects of the designer drug situation are completely different from what any of us have dealt with in the past. Let me give you some examples.

The cost of production is so low that for $2,000, millions of doses of designer drugs can be created. These doses can be sold by a dealer for $100 or for $1, and he or she would still make a profit because there is no middleman, and the designer drug operation is still in the hands of small entrepreneurs, rather than under the control of organized crime.

The potency of synthetic drugs can be thousands of times greater than that of the parent plant. For example, 3-methyl-fentanyl has been cited as being 1,000 times stronger than heroin. This is a uniquely American problem, with misuse of American technology responsible for the unconscionable crime of designer drug trafficking. We must take the steps needed to keep the designer drug problem from becoming the catastrophe that it has the potential to be.

The law enforcement community, the medical community, the education sector, and private industry can all be called upon to stop this problem before it poisons every State.

The administration's legislation takes a very large step in initiating this process. This far-reaching proposal will be discussed in detail by administration witnesses, who will testify later at this hearing.

In closing, I would like to make a personal observation. As chairman of both the Senate Subcommittee on Children, Family, Drugs

and Alcoholism, and the Senate drug enforcement caucus, I have been made aware of the scope, diversity, and destruction of illegal narcotics and have tried to counter just about every aspect of this intolerable situation. Designer drugs open up a 20th century Pandora's box of high-tech death and addiction. We must work together to save our children and our society from this newest of threats from drug abuse.

At this time we will receive for the record the opening statements of Senators Hatch, Kerry, and Dodd.

[The statements of Senators Hatch, Kerry, Grassley, and Dodd, follow:]

OPENING STATEMENT
SENATOR ORRIN G. HATCH
SUBCOMMITTE ON CHILDREN, FAMILY, DRUGS AND ALCOHOLISM
HEARING ON DESIGNER DRUGS

I COMMEND SENATOR HAWKINS FOR ADDRESSING THE TOPIC OF TODAY'S HEARING WHICH REPRESENTS A DISTURBING DEVELOPMENT. DRUG ABUSE HAS ALWAYS BEEN A MAJOR CONCERN AND PROBLEM IN OUR SOCIETY. NOW THE PROLIFERATION OF THE SO-CALLED "DESIGNER" OR SYNTHETIC DRUGS PRESENTS A NEW TWIST TO THIS THREAT.

FOR MOST OF THIS CENTURY THE UNITED STATES GOVERNMENT HAS ATTEMPTED TO CONTROL ILLEGAL DRUG TRAFFICKING BY TARGETING EFFORTS AT OUR BORDERS. INCREASINGLY THE DRUG MARKET IS BEING SUPPLIED FROM WITHIN OUR OWN BORDERS. UNDERGROUND LABORATORIES CONTINUALLY MANUFACTURE SYNTHETIC DRUGS WHICH ARE VIRTUALLY "TWINS" OF WELL-KNOWN DRUGS SUCH AS HEROIN AND COCAINE. THE EXTRAORDINARY FACT IS THAT, FOR THE MOST PART, THESE SYNTHETIC DRUGS ARE LEGAL.

IF A COMPOUND WITH A SPECIFIC CHEMICAL MAKE-UP IS NOT CLASSIFIED AS A CONTROLLED SUBSTANCE BY THE STATE OR FEDERAL GOVERNMENT, IT IS LEGAL TO PRODUCE AND EVEN TO USE WITH NO RESTRICTIONS. WHEN A SUBSTANCE, SUCH AS ALPHA-METHYL FENTANYL, A SYNTHETIC HEROIN, IS IDENTIFIED, THE DRUG ENFORCEMENT ADMINISTRATION CAN MOVE TO CLASSIFY IT AS AN ILLEGAL SUBSTANCE. HOWEVER, AS SOON AS THE NEWLY-CREATED DRUG IS ACTED AGAINST, A LEGAL VARIATION HAS BEEN DEVELOPED. IT IS A RELATIVELY

EASY TASK FOR A CHEMIST WITH EVEN A SMALL AMOUNT OF LABORATORY EXPERIENCE TO ALTER A COMPOUND'S COMPOSITION SLIGHTLY. THE ADDITION OF A SINGLE ELEMENT OR UNIT SUCH AS A METHYL GROUP TO A COMPOUND PRODUCES A COMPOUND WHICH IS THEN LEGAL. LEGITIMATE RESEARCH CHEMISTS HAVE DONE THIS FOR YEARS IN ORDER TO REDUCE SIDE-EFFECTS IN MEDICINAL DRUGS WITHOUT ALTERING THE THERAPEUTIC VALUE SIGNIFICANTLY. NOW, OTHER CHEMISTS EXPLOIT THESE SAME PROCESSES TO CIRCUMVENT THE LAW.

WE HAVE ALL PLEDGED A WAR ON ILLEGAL DRUGS. HOWEVER, WE MUST NOT LET THESE NEW "SYNTHETIC DRUGS" INVADE OUR SCHOOLS, OUR COMMUNITIES, BY DESTROYING OUR SOCIETY AND ESPECIALLY OUR YOUTH. IT IS ESSENTIAL THAT WE TAKE A CLOSE LOOK AT THIS PRESSING PROBLEM, ESPECIALLY IN LIGHT OF THE GRAVE NEW HEALTH HAZARDS APPEARING WITH THESE NEW DRUGS. IN ADDITION TO HEALTH RISKS, THE CRIME AND THE PERSONAL TRAGEDY THAT ACCOMPANY ILLICIT DRUGS MUST NOT FOLLOW WITH THE SPREAD OF THESE DESIGNER DRUGS. THE GREAT POTENTIAL FOR PROFIT, THE LOW RISK AND THE RELATIVE EASE OF PRODUCTION COULD EASILY RESULT IN A MARKETPLACE EXPLOSION WITH THESE FAR-REACHING EFFECTS.

I LOOK FORWARD TO THE TESTIMONY OFFERED TODAY. WE NEED TO SHED NEW LIGHT ON THIS SUBJECT SO THAT WE MAY FULLY UNDERSTAND THE PROBLEMS ASSOCIATED WITH "DESIGNER" OR SYNTHETIC DRUGS. I AM PLEASED THAT SENATOR PAULA HAWKINS IS LEADING THIS EFFORT AND I LOOK FORWARD TO PARTICIPATING WITH OTHERS ON THIS ISSUE TO ERADICATE THESE HARMFUL SUBSTANCES FROM OUR SOCIETY.

STATEMENT OF

SENATOR JOHN KERRY

BEFORE LABOR AND HUMAN RESOURCES

SUBCOMMITTEE ON CHILDREN, FAMILIES, DRUG

AND ALCOHOLISM

JULY 25, 1985

MADAM CHAIRMAN -- I am pleased you have called this hearing to address a most serious and timely issue -- use and abuse of Designer Drugs.

The alarming increase of this new drug abuse phenomenon could have disasterous consequences for our society, as it has already had on the lives of many individuals. As a former Massachusetts Assistant District Attorney, I am painfully aware of how resilient the drug abuse problem is in this country and Designer Drugs is the newest threat.

Black market chemists are modifying controlled substances to create substances not covered by the Controlled Substances Act, but which have the potency of the dangerous drugs the Act was created to control. The effects have been staggering especially among the heroin-like substances which have caused severe neurological impairment. In California, a substance known as MPTP was circulated as "new heroin" and it has caused brain damage similar to the final stage of Parkinson's disease. It is my understanding that most recently, some designer drug users are showing symptoms of Huntington's disease.

As the dimensions of this problem grows we have realized that current laws are unable to cope with both identifying and stopping the manufacturing and use of designer drugs. They are very difficult to detect in the body and the possible effect of each new batch is an unknown. Needless to say, they are not tested and the potential for the development of highly toxic compounds is very real.

Almost any university chemistry library can provide the necessary information for the manufacturing of designer drugs, and the cost of materials and space needed is minimal. Despite this fact, the street value of the final product can be worth thousands. And finally, current drug laws define illegal drugs by their exact molecular structure, so it is possible for individuals to evade the law by making minor changes in the substance's molecules.

I support efforts to respond to this problem through stiff federal legislation which will stem the manufacture, distribution, and possession of these very dangerous substances. I would like to state one concern that I have with regard to the language of new legislation. I believe great care must be taken to assure that the impact of strong new drug control language protects legitimate drug research and manufacturing. Although this problem has dangerous potential, we must cautiously review the best legal remedies while protecting future beneficiaries of medical drug advances.

I hope the Judiciary Committee, where pending designer drug legislation has been referred, will take up this concern soon and I am confident today's hearing will facilitate the proper review of new legislation.

OPENING STATEMENT OF SENATOR CHRISTOPHER J. DODD

Senator DODD. Madam Chairman, I am pleased that the subcommittee this morning is examining a potentially explosive problem in this country; namely, the production and abuse of designer drugs.

During our first subcommittee hearing on March 13 focusing on international narcotics trafficking, I raised the issue of designer drugs. I felt it was important within the context of that hearing to look at the extent to which the drug problem in this country is a result of domestic production and domestic trafficking. Designer drugs represent a potentially formidable means of the synthetic production of addictive and sometimes lethal substances.

Designer drugs first came to the attention of authorities in California in 1979, when several people die of overdosing on a synthetic form of heroin. By slightly altering molecular structures, chemists in illicit laboratories can produce a potentially infinitisimal number of harmful drugs. Such drugs are inexpensive to produce. Their use can lead to brain damage, paralysis, and even death. One researcher estimates that as many as one out of every five heroin addicts in California is a regular user of synthetic heroin.

The most alarming aspect of designer drugs is that, to date, it has been perfectly legal both to synthesize and to use them. Until a specific drug is classified by State or Federal Government as a controlled substance, its use and production remains legal. As a result, designer drugs could provide drug dealers with an alternative to importing heroin and cocaine from Southeast Asia and Latin America. For that reason, I questioned administration witnesses at our first subcommittee hearing about their efforts to combat designer drugs. To date, I have received no reply to my question so I welcome the testimony of the Drug Enforcement Administration this morning on this pressing issue.

Last year, Congress gave the Drug Enforcement Administration emergency scheduling powers, to enable them to speed up the process of classifying designer drugs as controlled substances. Yet further action is needed, as countless new drugs can be produced by just slightly altering a molecular pattern. I understand my colleague from California, Mr. Cranston, and my colleague from South Carolina, Mr. Thurmond, have introduced identical legislation to curb the production and use of designer drugs. I look forward to hearing the testimony of the witnesses this morning on this legislation and on further steps which must be taken both in research and enforcement.

Senator GRASSLEY. Madam Chairman, thank you for holding this hearing on designer drugs, and not only to look at the problems they bring, but to examine current efforts and suggestions of what can be done to curb this insidious threat to the health of our Nations young people.

I must add my concerns that even the term "designer drugs," brings with it a "mistique" of something new—an "in thing," which can encourage unsuspecting victims to experiment with substances which are unknown, and possibly deadly.

Nevertheless, in my own State of Iowa, there is little evidence of a "designer drug" problem—for which I am very thankful. Howev-

er, Iowa has the dubious distinction of having the largest heroin problem in its region. Should a synthetic substitute flood Iowa's heroin markets, the potential aggravation of drug user maladies could be disastrous.

Fentanyl—pronounced "fentanol"—analogs are extremely potent, and the synthetic heroin is several thousand times stronger and much cheaper to produce. As Mr. Lawn will testify, 1 kilogram could be "manufactured for under $2,000." The street value would be over $1 billion.

The clandestine production of these substances yields a number of byproducts and impurities which have caused paralysis and brain damage indistinguishable from Parkinson's disease. Many of these analogs have been cut with substances such as strychnine which has resulted among other things, in many deaths.

The phenomenon we have on our hands is a time bomb. Its consequences and dimensions could not be more frightening.

We know the Drug Enforcement Administration [DEA] has made substantial progress in controlling drug trafficking from abroad.

However, it is now possible for one chemist to produce the equivalent of the entire world's supply of heroin without ever harvesting a single opium poppy.

What used to be the province of powerful international drug syndicates, is now becoming a cottage industry. What used to take speed boats, airplanes, and so on, now takes a few test tubes, a bunson burner, a supply of easily obtained chemicals and an empty garage.

Parent, teachers, civic leaders, and ministers, have been warning and warning our young people about the dangers of using drugs. Part of that warning has always included the reminder that "you never know what you're buying or taking." Unfortunately, the nightmares that go with those warnings, could now come true on a massive scale with little chance of remedial or medical assistance for the user.

It is because of these concerns that I have just cosponsored S. 1437. We need to protect our young people from the clandestine chemists who are able to produce and distribute new chemical variants faster than they can be controlled and declared illegal.

Thank you, Madam Chairman.

Senator HAWKINS. Our first panel consists of Dr. Donald Ian MacDonald, Administrator of the Alcohol, Drug Abuse, and Mental Health Administration of the Department of Health and Human Services. Dr. MacDonald is one of our Nation's top health experts, and we are pleased to have him with us to comment on the Administration's efforts to find solutions to the problem of designer drugs.

I am particularly pleased to welcome Dr. MacDonald here today, as he is a fellow Floridian with nationally recognized expertise in narcotics control.

Testifying on the same panel is Robert J. Roberton, chief of the division of drug programs of the California Department of Alcohol and Drug Programs. We are very proud to have with us today the nationally recognized expert on the topic of designer drugs. We are especially pleased you could make this long trip to be here.

I welcome both of you gentlemen, and will ask Mr. Roberton to begin, please.

STATEMENT OF ROBERT J. ROBERTON, CHIEF, STATE OF CALIFORNIA DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS, DIVISION OF DRUG PROGRAMS, SACRAMENTO, CA, AND DR. DONALD IAN MacDONALD, ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MD

Mr. ROBERTON. Thank you, Madam Chairman.

I bring you greetings from Gov. George Deukmejian and Mr. Chauncey Veatch, the director of the Department of Alcohol and Drugs of the State of California.

Instead of reading my testimony, which would take up a lot of time, I will highlight some of the areas that I think are important. And Dr. MacDonald and I have agreed that we will try not do the same thing.

Just a little background on the fentanyl series. As you know, fentanyl, sublimaze, has been used in this country since 1968, when it was imported from Janssen Pharmaceuticals in Belgium, and it is a safe, short-acting narcotic analgesic that is very well respected.

The first we heard of any illegal activity surrounding fentanyl or fentanyl analogs was for doping race horses in the late sixties and early seventies. There was a prediction at that time that this would be great for humans if anyone sort of picked up the analog game. Nobody did at that time, but very shortly afterwards, they did.

In California so far, we have had 100-plus deaths from the fentanyl analogs, and it appears to be running about six or seven deaths per month, scattered throughout the State of California. At one time, we thought it was a suburbia drug, but a recent random sample of urines in drug programs in the large cities indicates that about 20 percent of heroin addicts there are also using the fentanyl analogs. And we have about 130,000 heroin addicts; 20 percent of them are using fentanyl analogs.

The first analog was in 1979 alpha-methyl-fentanyl in Orange County, and very quickly, law enforcement moved to schedule this analog.

One of the big problems we have is in toxicology, where the average lab would find it impossible with their present standards or would fail to indicate the presence of fentanyl. And we are talking about parts per billion in biological fluids, so it is a real problem for labs.

What this means is that treatment programs are admitting people who show all the classic signs of narcotic addiction, and when they test blood and urine they find nothing. We only have two labs capable of detection of the fentanyl analogs at the moment.

The same problem really exists for probation, parole, the military, where standard indicators would fail to indicate the use of any of the fentanyl analogs.

The people that we find using, apart from heroin addicts, are people who get into trouble with cocaine, who get the edges, who want to come down, and tend to look for something to flatten out their problem.

And when I say "analogs," really, I mean there is one specific on the street now, and that is 3-methyl-fentanyl, the one that you

mentioned, Madam Chairman. It is running between 1,000 to 3,000 times stronger than heroin.

The methods of administration are intravenous; you can snort it, you can smoke it. So again, we have another problem. The people who do not want to be identified with intravenous use can smoke it or snort it and get the same effect.

I will leave going into the strength of the fentanyl analogs until later.

One thing we have to remember is that fentanyl is not synonymous with the fentanyl analogs, and we have to be careful that people do not feel that fentanyl is the "bad guy" here. It is not. Fentanyl is a well-respected drug used in surgery. It is the analogs that we are talking about, the "designer" analogs.

If you can imagine, Madam Chairman, holding 200 grams in one hand, that is 200 million doses if it were to be sold on the streets of California. That is a lot of doses and a very small amount of material. A shoeboxful could supply half a million heroin addicts in this country for about 6 months. That is how small the material is. That is one of the big problems.

The color—we have seen it in every color in California. Whatever the market wants, that is the color that is made, sometimes it is white, and can be made to look like Mexican Brown heroin. It is sold as heroin. It is sold primarily as "China White," which is the best heroin you can get.

We feel that it is a state-of-the-art chemistry. And one of the problems with that is, of course, maybe he made enough to last for 10 years and retired or went away, and has it in his closet at home, and every so often puts a little out on the streets—who knows? Or maybe it is a chemist that continues to make small amounts. Maybe it is more than one chemist.

In California, we tend to believe there is one chemist who I think is being called, quote, "the evil genius." In California, we tend to have the entrepreneurial chemists that make the designer drugs. It seems that most of the designer drugs start in California, unfortunately, so goes California, so goes the rest of the Nation.

The second drug that we have is somebody tried to make Demerol, or MPPP, (a mepiridine analog) and really they missed. It was probably because of a changed reaction time, or they may have overheated it. Part of the material became MPTP, which is a neurotoxin. This is completely separate from the fentanyl series of analogs.

In a minute, there are six minutes of film which will show exactly what happens with this second one. Fentanyl kills people with massive overdose death. The MPTP is a neurotoxin that destroys brain cells, that cripples people for life. So there are two distinct drugs we are talking about here. MPTP kills the cells in the substantia nigra which, in essence, are the same cells that die in Parkinson's disease in old people.

The route of administration was intravenous, the same. The addicts talk about a "spacey" feeling when they injected it; hallucinations; some of them talk about a burning sensation, not only at the point of injection, but all over their bodies. Again, it was sold as a China White, or heroin, on the street.

The clients that have been seen—and we have about 400 now identified that have used this material—many of them confirmed chronic Parkinson's disease—they have the same signs and symptoms, the shuffling gate, the seborrheic changes, oily skin, rigidity, tremors, the cogwheeling of the joints, drooling, difficulty in speaking--all the classic signs of Parkinson's disease. In fact, they are treated with L-DOPA and bromacryptine etc. the same way as those with Parkinson's disease.

One of the problems is that the medication that is used seems to last only a short period of time, and they become very toxic from the medication. This requires people to be brought into the hospital, some of them in intensive care. I can think of one patient in particular that cost $15,000 a month in intensive care. Unfortunately, these people tend to end up in county hospitals, and it is a large expense, if we are faced with what we call "drug holidays," where you have to bring people in, stop all medication, let them freeze up, and then start their dosage again.

The batch of this MPTP material was on the streets in 1982, and people are still showing up now. Some of them showed up right away; others, as I say, are still coming in now with signs and symptoms of Parkinson's disease.

The Center for Disease Control has been a tremendous help to us in the State of California and also Dr. Bill Langston, chief of neurology at the Santa Clara Valley Medical Center, in helping us identify how we are going to track and threat these people, how we are going to test the samples on the street. I would like to thank them publicly for that support and untiring effort.

One of the other problems we have found in California is some of these people were misdiagnosed. They ended up in hospitals, being admitted as catatonic schizophrenics. Some of them froze up at home. Some of them froze up on the freeway.

My prediction for the future is that we are going to have more neurodegenerative diseases, more experimentation, because of the vast amount of dollars involved.

Recently I was asked did I think organized crime was involved in the designer drugs. I really do not know. One of the things that I think about is that if 20 percent of the addicts in California are using fentanyl analogs, it is making a dent in somebody's market, whether it is organized crime or anybody else. I would imagine that organized crime would not like the fentanyl analogs because it interferes with their infrastructure and the structure of other communities in other countries—that is speculation on my part. Maybe we are going to have drug wars because of this.

In the State of California, Dr. Filante, an assemblyman, who is a physician, has introduced legislation which hopefully will control some of the fentanyl analogs and put them in schedule I, which means they have no legitimate medical use.

One last comment, Madam Chairman. I think the word, designer drugs, should be dropped. I think it is very bad. I think of my two children, who buy designer shirts, designer jeans, designer shoes, and they have their logos. I would hate for my kids to feel that designer drugs are OK to use. So I think it is a real problem. In California, we have gotten away from designer, and we are just calling them synthetic drugs now.

Lastly, I would like to just show you 6 minutes of a movie that I made on MPTP, with Bill Langston, just to show you how dramatic and how affected people are.

This movie was made specifically to show to addicts who are in treatment in California, because we wanted them to know what they were buying on the streets—and it has been edited down from just over 15 minutes to over 6 minutes.

[Videotape shown.]

VOICE OF MR. ROBERTON. This is what happens when a user accidentally takes the fake heroin, MPTP.

Meet George. He did not realize at the time that his dope was really a synthetic, a drug cooked up in a chemist's lab and then sold on the street as heroin to hundreds of unsuspecting users

George now suffers from Parkinson's, a disease of the nervous system that has no cure and renders its victims virtually helpless.

It looks like MPTP is a walking time bomb, causing symptoms that can show up immediately, or in 6 months, or maybe even years down the road. The condition is permanent and requires medication and treatment for the rest of the patient's life—if the patient lives.

I am Robert Roberton, chief of the division of drug programs for the State of California.

It is not just MPTP that is risky. You are putting your life on the line every time you score a drug off the street. Drug users are guinea pigs. There is simply no way to know until after you take it whether your dope is bad. And when kitchen chemists mix up a batch of MPTP, dealers still hustle it on the street because it brings an enormous profit.

Remember, there are no quality controls in this business. They don't care if they cut the dope with battery acid.

Take MPTP. It is a known poison when injected. However, it is sold to pharmaceutical companies, who use it to manufacture other chemicals. Since the drug is perfectly legal, these kitchen chemists stay one step ahead of the law.

MPTP is a cousin of Demerol. Demerol can kill you instantly if you overdose. MPTP causes a painful, slow death, quickly destroying brain cells and making it impossible to move or walk or talk normally.

This is what happens.

When MPTP is injected, it burns as it travels through the vein of the arm. When it reaches the heart, the drug is mixed with blood from all over the body. It then leaves the heart, travels through the lungs, and then back to the heart, before taking a major artery to the brain.

Although MPTP reaches all parts of the brain, it only damages the substantia nigra, a very small area that sits atop the brainstem. This area controls how we move.

The substantia nigra is a pigmented area, dark in color. When these cells are damaged by MPTP and die, this pigment disappears. Normally, we stand with an upright, relaxed posture. With early Parkinson's caused by MPTP, things begin to change. Muscles stiffen and ache; the body becomes slightly bent, and there is a shakiness in the hands.

As the disease progresses, the arms and legs become more bent; the tremor in the hands becomes more obvious, and the body slows down as walking becomes difficult. Later on, the arms and legs contract, and tremors become severe. The body is aging quickly and, instead of normal, healthy strides, walking is reduced to a short-step, shuffling gate.

At this point in the disease, symptoms grow worse. The whole body hunches over; just standing is difficult, and patients fall easily. Medication is constantly required and can relieve only some of the symptoms.

Dr. Bill Langston, Chief of Neurology at the Santa Clara Valley Medical Center, has been treating patients with this unique form of Parkinson's for the past three years.

VOICE OF DR. LANGSTON. One of the real pieces of bad news is that probably even one injection is enough to cause some symptoms or signs.

A VOICE. My daughter and her husband—all three of us took it together, and now, all I can think about is that we all have the disease, Parkinson's Disease. And the first time I heard about it, all I could think about was all of us dying.

VOICE OF MR. ROBERTON. How can you tell if your street dope is bad? There are a number of telltale symptoms.

A VOICE. When I did the drug, I heard the buzzing sound, like I had done cocaine, and that is what I felt like when I did it the first time. And I only did it one time.

A VOICE. When I first injected the synthetic heroin, I had a burning sensation. It started from the point of injection all the way through my whole body—and the explosion of tastes that came out of my mouth, you know, the chemical tastes.

A VOICE. The first time I did it, it was pink, and it dissolved real fast in the water. It burned when it went in my arm. And then, the rush was real strong. I thought I was going to pass out, so I had to fight to stay conscious. But then, I thought, wow, it must be good, because it was so strong, you know.

VOICE OF DR. LANGSTON. At first, we thought synthetics would look different than real heroin. We have since learned that dealers can easily change the appearance of any of these substances so you cannot tell whether this is synthetic or real by the way it looks. That is very important.

It is critical that if you used MPTP in the past, but feel fine now, that you still get help. We think the symptoms could show up months or even years later. And unless we know about you and your case, if we find ways to prevent this, we will not be able to reach you.

Mr. ROBERTON. The Romero family is fortunate. Their Parkinson's is in check.

George is not so lucky.

VOICE OF GEORGE. [Inaudible comments.] This stuff is killing me.

[Conclusion of videotape.]

Mr. ROBERTON. That is just a very small sample of the kinds of problems that we are facing in California.

One of the last problems I want to talk about is having labs that can detect the fentanyl analogs--and others. We only have two at the moment. One is the DEA, Drug Enforcement Administration, lab, and the other one is run by Gary Henderson at the University of California at Davis. These are the only two labs that can detect fentanyl in powder form and biological fluids. That is a real problem.

As designer drugs spread across the United States, we do need a network of labs with the ability to detect these substances.

I will end my statement on that point.

[The prepared statement of Mr. Roberton follows:]

STATEMENT OF ROBERT J. ROBERTON, CHIEF, DIVISION OF DRUG PROGRAMS, DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS, STATE OF CALIFORNIA

MAY I BEGIN BY SAYING THAT I AM PLEASED TO HAVE THE OPPORTUNITY TO APPEAR BEFORE YOU AND I BRING YOU GREETINGS FROM THE STATE OF CALIFORNIA AND CHAUNCEY L. VRATCH III, DIRECTOR, DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS.

DESIGNER DRUGS

THE ANALOG GAME

THE TERM "DESIGNER DRUGS" WAS ORIGINALLY COINED IN THE LABORATORY OF DR. GARY HENDERSON AT THE UNIVERSITY OF CALIFORNIA, DAVIS. IT WAS ORIGINALLY MEANT TO REFER TO THE INCREASING SOPHISTICATION OF CHEMISTS IN ILLICIT LABORATORIES WHO ARE NOW APPROACHING THE ABILITY TO PRODUCE DRUGS DESIGNED TO FIT THE TASTES OF INDIVIDUAL CLIENTS.

DESIGNER DRUGS ARE BEGINNING TO PLAY A MORE PROMINENT ROLE IN THE HEROIN ADDICTS MARKET PLACE. FENTANYL ANALOGS ARE BEING SOLD AS "CHINA WHITE", "SYNTHETIC HEROIN", ETC. AND ARE BEING ASKED FOR BY ADDICTS ON THE STREET. AVAILABILITY AND PRICE ARE ATTRACTIVE TO THE HEROIN USER, SOME WHO FEEL THEY MAY CONTAIN LESS ADULTERANTS THAN HEROIN.

OUR DATA COLLECTION ADMISSIONS ALSO SHOW AN ALARMING INCREASE OF APPROXIMATELY 20% IN THE USE OF HEROIN AS THE PRIMARY DRUG BY THOSE 17 YEARS OF AGE OR YOUNGER. OVER 50% OF ALL ADMISSIONS TO PUBLIC PROGRAMS IN THE STATE OF CALIFORNIA ARE FOR THE PRIMARY DRUG OF HEROIN.

FENTANYL

THE FENTANYLS ARE A CLASS OF VERY POTENT NARCOTIC-ANALGESICS ORIGINALLY SYNTHESIZED BY THE JANSSEN PHARMACEUTICAL COMPANY OF BELGIUM. ALTHOUGH THE CHEMICAL STRUCTURES OF THESE DRUGS ARE QUITE DIFFERENT FROM THE OPIATES AND OPIOIDS; THE FENTANYLS, NEVERTHELESS, POSSESS ALL THE PHARMACOLOGICAL AND TOXICOLOGICAL ACTIONS OF THE CLASSICAL NARCOTICS. FENTANYL, THE PARENT DRUG, IS USED EXTENSIVELY IN CLINICAL MEDICINE AS AN INTRAVENOUS ANALGESIC-ANESTHETIC UNDER THE TRADE NAME SUBLIMAZE. IT IS A WELL RESPECTED DRUG.

BEGINNING IN 1979, ILLICITLY SYNTHESIZED DERIVATIVES OF FENTANYL BEGAN APPEARING ON THE STREETS AS DRUGS OF ABUSE UNDER THE NAME "CHINA WHITE", THE NAME USUALLY ASSOCIATED WITH VERY PURE SOUTHEAST ASIAN HEROIN. SOON THEREAFTER A SERIES OF DEATHS OCCURRED IN SOUTHERN CALIFORNIA WHICH LOOKED LIKE TYPICAL HEROIN OVERDOSE DEATHS EXCEPT THAT TOXICOLOGICAL ANALYSIS FAILED TO DETECT ANY NARCOTIC. TO DATE OVER 100 SUCH DEATHS HAVE OCCURRED.

THE LABORATORY AT UC DAVIS, PARTIALLY SUPPORTED BY THE CALIFORNIA STATE DEPARTMENT OF ALCOHOL AND DRUG PROGRAMS, IS USING VERY SENSITIVE ANALYTICAL TECHNIQUES SPECIFIC FOR THE FENTANYLS, HAS DETECTED VARIOUS FENTANYL DERIVATIVES IN THE BODY FLUIDS OF THE OVERDOSE VICTIMS. IN ADDITION, THEY HAVE DETECTED THE FENTANYLS IN THE URINE OF A SIGNIFICANT NUMBER OF INDIVIDUALS ENROLLING IN VARIOUS METHADONE AND OTHER DRUG TREATMENT PROGRAMS THROUGH OUT CALIFORNIA.

TO DATE THEY HAVE IDENTIFIED TEN DIFFERENT FENTANYL DERIVATIVES, IN ADDITION TO FENTANYL ITSELF, IN SAMPLES BEING SOLD ILLICITLY UNDER A VARIETY OF NAMES

SUCH AS "CHINA WHITE", "SYNTHETIC HEROIN" AND "FENTANYL". THE NEWEST DERIVATIVE, 3-METHYL FENTANYL, IS EXTREMELY POTENT (APPROXIMATELY 7000 TIMES AS POTENT AS MORPHINE) AND IS THOUGHT TO BE RESPONSIBLE FOR AN ALARMING NUMBER OF RECENT OVERDOSE DEATHS IN THE SAN FRANCISCO BAY AREA.

FENTANYL DERIVATIVES USED MEDICALLY (FIGURE 1)

A BRIEF DESCRIPTION OF THE FENTANYL DERIVATIVES USED IN HUMAN AND VETERINARY MEDICINE IS GIVEN BELOW:

FENTANYL

FENTANYL WAS INTRODUCED INTO THE UNITED STATES IN 1968 AS AN INTRAVENOUS ANALGESIC-ANESTHETIC UNDER THE TRADENAME SUBLIMAZE® OR INNOVAR® (THE COMBINATION OF FENTANYL OR DROPERIDOL).(R-1) FENTANYL NOW OCCUPIES A MAJOR PLACE IN THERAPEUTICS AS A PREANESTHETIC MEDICATION, AN ANESTHETIC, AND A POST-SURGICAL ANALGESIC. FENTANYL IS VERY POTENT (APPROXIMATELY 100 TIMES AS POTENT AS MORPHINE) AND SHORT ACTING (DURATION OF ACTION IS APPROXIMATELY 70 MINUTES). IT IS A VERY IMPORTANT DRUG CLINICALLY AND IS PROBABLY USED IN OVER 70% OF ALL SURGERIES IN THE UNITED STATES.(R-2)

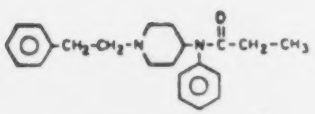
SUFENTANYL

SUFENTANYL IS AN EXTRAORDINARILY POTENT DERIVATIVE (2000-4000 TIMES MORPHINE) USED AS AN ANESTHETIC-ANALGESIC AGENT FOR CARDIAC SURGERY.

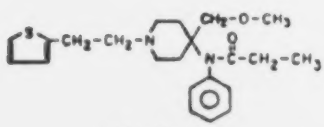
ALFENTANYL

ALFENTANYL IS A VERY SHORT ACTING (15 MIN.), SLIGHTLY LESS POTENT DERIVATIVE (20-30 TIMES MOPPHINE) CURRENTLY IN CLINICAL TRIALS AS AN ULTRA-SHORT ACTING ANALGESIC TO BE USED IN DIAGNOSTIC, DENTAL, AND MINOR SURGICAL PROCEDURES.

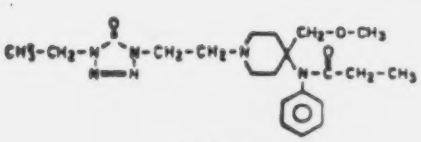
FIGURE 1



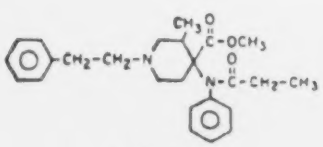
fentanyl (Sublimaze®)



sufentanyl



alfentanyl



lofentanyl

LOFENTANYL

LOFENTANYL IS EXTREMELY POTENT (6000 TIMES MORPHINE) AND VERY LONG ACTING AND IS BEING EVALUATED FOR USE WHEN PROLONGED ANALGESIA AND RESPIRATORY DEPRESSION ARE REQUIRED SUCH AS IN TETANUS AND MULTIPLE TRAUMA.

CARFENTANYL

CARFENTANYL IS A VERY POTENT ANALOG (3200 TIMES MORPHINE) WHICH IS USED ONLY IN "CAPTURE GUNS" FOR IMMOBILIZING WILD ANIMALS.

THE ILLICIT ANALOGS (FIGURE 2)

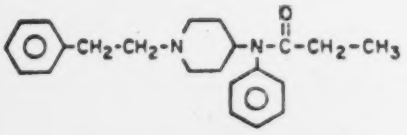
VERY LITTLE IS KNOWN ABOUT THE BIOLOGICAL EFFECTS OF THE ILLICT DERIVATIVES. AT BEST ONLY PRELIMINARY DATA IS AVAILABLE FROM STUDIES CONDUCTED IN LABORATORY ANIMALS. VIRTUALLY NOTHING IS KNOWN ABOUT THEIR EFFECTS IN MAN.

ALPHA-METHYL FENTANYL

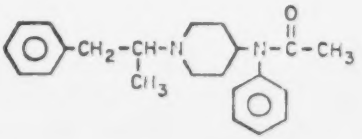
ALPHA-METHYL FENTANYL WAS THE FIRST ILLICIT FENTANYL DERIVATIVE TO APPEAR ON THE STREETS. IT IS A VERY SIMPLE MODIFICATION OF THE FENTANYL STRUCTURE AND IS ABOUT 200 TIMES AS POTENT AS MORPHINE. AS A NEW DRUG ENTITY IT WAS NOT AT FIRST ON ANY INTERNATIONAL, FEDERAL OR STATE RESTRICTED DRUG LIST AND WAS IN ESSENCE "STREET LEGAL". HOWEVER, IT IS NOW CLASSIFIED AS A SCHEDULE I DRUG (NO APPROVED MEDICAL USE AND HIGH ADDICTION LIABILITY) BY THE D.E.A.

PARA-FLOURO FENTANYL

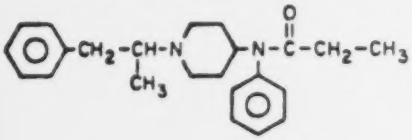
PARA-FLOURO FENTANYL WAS THE SECOND ILLICIT DERIVATIVE TO APPEAR ON THE STREETS. IT IS A VERY SIMPLE DERIVATIVE OF FENTANYL AND HAS ABOUT THE SAME POTENCY. IT IS PRESENTLY CLASSIFIED AS A SCHEDULE I DRUG BY THE D.E.A. LITTLE IS KNOWN ABOUT THIS COMPOUND. IT APPEARED ONLY BRIEFLY AND DOES NOT SEEM TO BE IN USE AT THIS TIME.



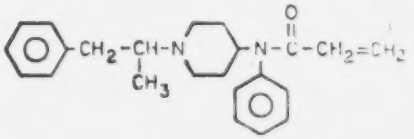
fentanyl (Sublimaze®)



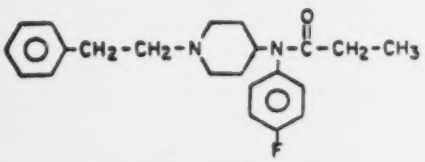
acetyl alpha-methyl fentanyl



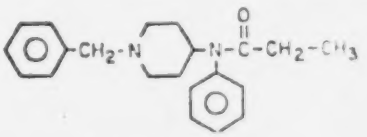
alpha methylfentanyl



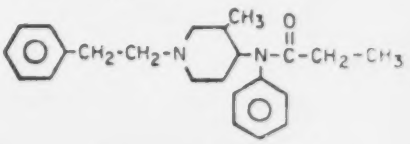
acryl alpha-methyl fentanyl



para-fluoro fentanyl



benzyl fentanyl



3-methyl fentanyl

FIGURE 2

ALPHA-METHYL ACETYLFENTANYL

ALPHA-METHYL ACETYLFENTANYL FIRST APPEARED ON THE STREETS IN 1983. THIS ALSO IS A VERY SIMPLE DERIVATIVE OF FENTANYL. BUT BECAUSE TECHNICALLY IT IS A NEW CHEMICAL ENTITY. IT ESCAPES CLASSIFICATION AS A RESTRICTED DRUG. AT THIS TIME IS IS NOT A RESTRICTED DRUG. NOTHING IS KNOWN ABOUT ITS PHARMACOLOGICAL PROPERTIES.

ALPHA-METHYL FENTANYL ACRYLATE

ALPHA-METHYL FENTANYL ACRYLATE (THIS IS A TRIVIAL. NOT A COMMONLY ACCEPTED OR GENERAL NAME) HAS BEEN IDENTIFIED IN SAMPLES CONTAINING ACETYL ALPHA-METHYL FENTANYL. IT MAY BE A NEW DERIVATIVE BUT IS MORE LIKELY A CONTAMINANT OR A BY-PRODUCT OF SYNTHETICS. NOTHING IS KNOWN ABOUT ITS PHARMACOLOGICAL PROPERTIES.

BENZYL FENTANYL

BENZYL FENTANYL HAS RECENTLY APPEARED MIXED WITH OTHER FENTANYL DERIVATIVES IN STREET SAMPLES. IT IS POSSIBLY AN UNWANTED SYNTHETIC BY-PRODUCT OR AN INTERMEDIATE USED IN THE SYNTHESIS OF OTHER FENTANYL DERIVATIVES. IT HAS NO NARCOTIC EFFECTS.

FENTANYL

FENTANYL ITSELF HAS APPEARED IN STREET SAMPLES AND HAS BEEN ASSOCIATED WITH OVERDOSE DEATHS IN CALIFORNIA. IT IS MOST LIKELY THAT THE FENTANYL SOLD ON THE STREETS IS SYNTHESIZED IN ILLICIT LABORATORIES AND NOT DIVERTED FROM PHARMACEUTICAL SUPPLIES. ALL FENTANYL SOLD ON THE STREETS IS IN POWDER FORM

AND ALL FENTANYL SOLD AS A PHARMACEUTICAL IS IN DILUTE, LIQUID FORM. ABUSE OF SUBLIMAZER IN HOSPITALS AND CLINICS BY MEDICAL PERSONNEL HAS BEEN DOCUMENTED BUT THE EXTENT OF THE PROBLEM IS KNOWN. (P-3)

3-METHYL FENTANYL

3-METHYL FENTANYL IS THE LATEST DERIVATIVE TO BE INTRODUCED ONTO THE STREETS AND IT IS CERTAINLY ONE OF THE MOST POTENT OF THE FENTANYLS (7000 TIMES AS POTENT AS MORPHINE). THIS ANALOG APPEARED IN CALIFORNIA SOMETIME BETWEEN THE FALL OF 1983 AND THE SPRING OF 1984 AND IS THOUGHT TO BE RESPONSIBLE FOR A OVER A DOZEN RECENT OVERDOSE DEATHS IN THE SAN FRANCISCO BAY AREA, THE HIGHEST INCIDENCE OF FENTANYL-RELATED DEATHS TO DATE.

PHYSICAL DESCRIPTION OF "CHINA WHITE"

THE FENTANYLS ARE CUT (DILUTED) WITH LARGE AMOUNTS OF LACTOSE OR SUCROSE (POWDERED SUGAR) BEFORE THEY ARE SOLD ON THE STREET SO THE AMOUNT OF ACTIVE DRUG PRESENT IS EXCEEDINGLY SMALL, LESS THAN 1%. THESE AMOUNTS ARE SO SMALL THEY CONTRIBUTE NOTHING TO THE COLOR, ODOR OR TASTE OF THE SAMPLE.

COLOR

THE COLOR OF THE SAMPLES OBTAINED TO DATE HAS RANGED FROM PURE WHITE (SOLD AS "PERSIAN WHITE") TO LIGHT TAN (SOLD AS "CHINA WHITE", "SYNTHETIC HEROIN", OR "FENTANYL") TO LIGHT BROWN (SOLD AS "MEXICAN BROWN"). THE BROWN COLOR COMES FROM THE LACTOSE WHICH HAS BEEN HEATED AND HAS CARAMELIZED SLIGHTLY.

TEXTURE

THE TEXTURE OF THE SAMPLES OBSERVED IN THE LABORATORY HAS RANGED FROM LIGHT AND FINELY POWDERED TO SOMEWHAT COARSE, CAKELIKE AND CRUMBLY, SOMEWHAT RESEMBLING POWDERED MILK.

ODOR

OCCASIONAL SAMPLES WILL HAVE A MEDICINAL OR CHEMICAL ODOR, BUT THIS IS NOT CHARACTERISTIC.

IN SUMMARY, THE FENTANYLS APPEAR IN ALL THE VARIOUS FORMS THAT HEROIN DOES AND THERE IS NOTHING CHARACTERISTIC ABOUT THE APPEARANCE OF ANY SAMPLE THAT WILL IDENTIFY IT AS FENTANYL.

ROUTES OF ADMINISTRATION

INTRAVENOUS INJECTION IS THE MOST COMMON ROUTE OF ADMINISTRATION FOR THE FENTANYLS; HOWEVER THEY ALSO MAY BE SMOKED OR SNORTED. IN FACT BECAUSE OF THEIR HIGH LIPID SOLUBILITY, THE FENTANYLS SHOULD BE EXCELLENT DRUGS FOR SNORTING AND MAY BECOME INCREASINGLY POPULAR DRUGS AMONG COCAINE USERS. AT LEAST ONE OVERDOSE FATALITY WAS IDENTIFIED IN WHICH SNORTING WAS THE ONLY ROUTE OF ADMINISTRATION. WE HAVE ALSO BEEN ABLE TO DETECT FENTANYL IN THE URINE OF INDIVIDUALS WHO USED THE DRUG ONLY BY SMOKING IT.

PHARMACOLOGICAL EFFECTS

IT SHOULD BE REMEMBERED THAT ALTHOUGH THE FENTANYLS ARE CHEMICALLY QUITE DISTINCT FROM OTHER NARCOTICS (MORPHINE, HEROIN, METHADONE, ETC.), THEY ARE PHARMACOLOGICALLY EQUIVALENT; THAT IS THEY HAVE ALL THE EFFECTS, SIDE EFFECTS AND TOXIC EFFECTS OF THE CLASSICAL NARCOTIC. THEREFORE ALL THE ACTIONS OF THE FENTANYLS CAN BE REVERSED BY NALOXONE (NARCAN®), ALTHOUGH HIGHER DOSES OF THE ANTAGONIST MAY BE REQUIRED.

EUPHORIA

THE EUPHORIA OR "RUSH" FROM THE FENTANYLS SHOULD BE QUALITATIVELY SIMILAR TO THAT OF HEROIN AND THE INTENSITY OF THE EFFECT WOULD DEPEND UPON THE DOSE AND THE PARTICULAR DERIVATIVE USED.

ANALGESIA

PROFOUND ANALGESIA (ABSENCE OF PAIN) IS A CHARACTERISTIC EFFECT OF ALL THE FENTANYLS. AS LITTLE AS 50 MICROGRAMS OF FENTANYL WILL PRODUCE ANALGESIA WHILE ONLY 7 MICROGRAMS OF THE 3-METHYL DERIVATIVE WOULD BE REQUIRED.

SIDE EFFECTS AND TOXICITY

RESPIRATORY DEPRESSION

RESPIRATORY DEPRESSION IS THE MOST SIGNIFICANT ACUTE TOXIC EFFECT OF THE FENTANYLS. THE DEPTH AND DURATION OF RESPIRATORY DEPRESSION WILL DEPEND ON THE DOSE AND THE DERIVATIVE USED. HOWEVER, COMPARED WITH OTHER NARCOTICS THIS

EFFECT IS RELATIVELY SHORT-LIVED. FOR EXAMPLE, FOLLOWING 200 MICROGRAMS OF FENTANYL GIVEN INTRAVENOUSLY MAXIMUM DEPRESSION OCCURS WITHIN 5-10 MINUTES, AND NORMAL RESPIRATION RETURNS WITHIN 15-30 MINUTES.

ANTIDOTE

NALOXONE (NARCAN®) IS THE ANTIDOTE OF CHOICE FOR RESPIRATORY DEPRESSION (OR ANY OTHER EFFECT) PRODUCED BY THE FENTANYLS

BRADYCARDIA

FENTANYL PRODUCES A DOSE-DEPENDENT DECREASE IN HEART RATE OF UP TO 25% WITH A PARALLEL DROP IN BLOOD PRESSURE OF UP TO 20%. THIS EFFECT IS THOUGHT TO BE DUE TO VAGAL STIMULATION AND CAN BE BLOCKED BY ATROPHINE. THE ROLE OF THIS RESPONSE, IF ANY, IN OVERDOSE DEATHS IS NOT KNOWN.

MUSCLE RIGIDITY

MUSCLE RIGIDITY, PARTICULARLY IN THE CHEST WALL, SOMETIMES CALLED "WOODEN CHEST" IS A RESPONSE COMMON TO HIGH DOSES OF ALL NARCOTICS. INDIVIDUALS USING THE FENTANYLS MAY DESCRIBE THIS EFFECT AS A MUSCLE TIGHTNESS OR TINGLING.

ADDICTION LIABILITY

THE FENTANYLS PRODUCE BOTH TOLERANCE AND PHYSIOLOGICAL DEPENDENCE FOLLOWING REPEATED ADMINISTRATION. CONTROLLED STUDIES HAVE SHOWN THAT ADDICTS PERCEIVE FENTANYL SUBJECTIVES AS HAVING HEROIN-LIKE EFFECTS. IN CALIFORNIA WE HAVE FOUND MANY INDIVIDUALS ENROLLING IN METHADONE TREATMENT PROGRAMS WHO HAVE ONLY

FENTANYL IN THEIR URINE UPON ADMISSION. YET ARE CONVINCED THEY USE ONLY VERY HIGH GRADE HEROIN. THEREFORE WHEN PHARMACOLOGICALLY EQUIVALENT DOSES ARE USED, MOST USERS PROBABLY CANNOT TELL THE DIFFERENCE BETWEEN HEROIN AND THE FENTANYLS.

Abuse Potential

FENTANYL AS A PHARMACEUTICAL (SUBLIMAZE®) WAS ALWAYS THOUGHT TO HAVE A LOW ABUSE POTENTIAL BECAUSE OF ITS SHORT DURATION OF ACTION AND ITS RESTRICTED AVAILABILITY. ALSO, SUBLIMAZE® IS AVAILABLE ONLY IN INJECTABLE, AQUEOUS FORMULATIONS CONTAINING EITHER 100 MICROGRAMS OR 500 MICROGRAMS PER VIAL (50 MICROGRAMS/MILLITER). THESE RELATIVELY SMALL AMOUNTS AND LOW CONCENTRATIONS MAKE IT DIFFICULT FOR A TOLERANT ADDICT TO ADMINISTER A EUPHORIC DOSE CONVENIENTLY.

UNTIL NOW, THE ONLY DOCUMENTED ILLICIT USE OF FENTANYL WAS IN "DOPING" RACE HORSES. NARCOTICS ARE FREQUENTLY USED TO DOPE HORSES BECAUSE THEY PRODUCE EXCITATION IN THE HORSE (AND OTHER ANIMALS SUCH AS THE CAT AND MOUSE). FENTANYL'S SHORT DURATION OF ACTION AND ITS VERY LOW, DIFFICULT TO DETECT, CONCENTRATIONS IN BLOOD AND URINE MAKE IT AN IDEAL DOPING AGENT. FENTANYL HAS BEEN USED IN THIS MANNER FOR NEARLY A DECADE.

NOW THE FENTANYLS ARE AVAILABLE THROUGHOUT MOST OF CALIFORNIA AND BECAUSE THEY ARE POTENT, NOT DETECTED BY ROUTINE ANALYTICAL METHODS, AND, IN THE CASE OF THE NEWER ANALOGS, QUITE LEGAL, THEY MAY BECOME THE DRUG OF CHOICE FOR MANY HEROIN USERS. IT IS OUR OPINION THAT FENTANYL USE WILL INCREASE IN CALIFORNIA, ITS USE WILL SPREAD TO OTHER STATES, AND THAT NEW DERIVATIVES WILL APPEAR PERIODICALLY.

Overdose Deaths

To date the laboratory has identified 100 overdose deaths caused by the fentanyls. Nearly all of these cases occurred in California; however, two recent deaths occurred in Oregon which suggests that fentanyl use may be spreading to other states. All cases were similar in that they involved known heroin users, injection sites and accompanying paraphernalia were found, and autopsy showed typical signs of narcotic overdose such as pulmonary edema and congestion. Routine toxicological analysis of the body fluids revealed no narcotics, sedative or stimulant drugs present; however, analysis of these fluids in the laboratory using methods specific for the fentanyls revealed very low levels of these drugs. Traces of the fentanyls were also found in the accompanying paraphernalia.

Fentanyl-related deaths have occurred in nearly every urban area in California, in suburban areas, and even in semi-rural areas. Ages of the victims ranged from 20-40 years. Most were male, although 9 were female. Most of the victims were white; but there were significant numbers of Hispanics and blacks. In short, fentanyl use is not confined to any geographical area or any social, economic or ethnic group, but is distributed widely throughout the heroin using population.

Analysis of Samples for China White

The fentanyls are very difficult to detect either in body fluids or paraphernalia because the amounts present are very small and because they do not react with the reagents routinely used for the analysis of narcotics. The

FEW METHODS AVAILABLE ARE LISTED IN REFERENCES 9-12.

WHY DO THEY REPRESENT SUCH A HAZARD AND PUBLIC HEALTH PROBLEM? THERE ARE SEVERAL CLEAR-CUT REASONS. FIRST, THESE DRUGS DO NOT REQUIRE IMPORTATION AND ALL THE COSTS AND EXPENSES THEREBY INCURRED. SECONDLY, THEY ARE MUCH LESS EXPENSIVE TO MAKE. THIRDLY, OF COURSE, THOSE MAKING AND SELLING SYNTHETICS MAY NOT BE PROSECUTED BECAUSE THE SUBSTANCE MAY NOT BE ILLEGAL. FORTUNATELY, THE DEA HAS RECENTLY BEEN ABLE TO TAKE SWIFT ACTION TO CONTROL SOME OF THESE SUBSTANCES. LET ME GIVE SOME EXAMPLES. IT IS ESTIMATED THAT A SINGLE CHEMIST WORKING AN EIGHT HOUR DAY COULD, USING THE MORE POTENT FENTANYL DERIVATIVES, SUPPLY THE ENTIRE NATION'S HEROIN SUPPLY ON AN ON-GOING BASIS. A SINGLE 6 MONTH SUPPLY FOR THE UNITED STATES COULD BE STORED IN A CLOSET. HENCE, ONE CAN SEE THE IMMENSE ATTRACTIVENESS OF THIS APPROACH IN TERMS OF COST AND LIABILITY TO THOSE ON THE PRODUCTION SIDE OF THE ILLICIT DRUG MARKET.

WHAT ARE THE HAZARDS? THERE ARE BASICALLY THREE. FIRST, THESE CHEMISTS ARE OBVIOUSLY NOT REQUIRED TO CARRY OUT SAFETY TRIALS WITH THESE NEW COMPOUNDS AS A LEGITIMATE DRUG COMPANY WOULD BE. HENCE, THE FIRST SUBJECTS TO RECEIVE THEM ARE NOT LABORATORY ANIMALS, BUT HUMAN BEINGS USING THESE COMPOUNDS ON THE STREET. SECONDLY, THERE ARE NO QUALITY CONTROLS IN THESE LABORATORIES AS THERE WOULD BE IN A LEGITIMATE DRUG COMPANY. HENCE, CONTAMINANTS OR UNWANTED COMPOUNDS ARE NOT REMOVED, AND PROBABLY OFTEN NOT EVEN DETECTED. THIRDLY THERE IS THE ISSUE OF POTENCY. THE FENTANYL VARIANTS, FOR INSTANCE, MUST BE CUT IN MICROGRAM AMOUNTS. TO GIVEN AN EXAMPLE OF HOW SMALL AN AMOUNT THIS IS, A POSTAGE STAMP WEIGHS ABOUT 60,000 MICROGRAMS. HENCE, OVERDOSES ARE COMMON, AND THE FENTANYL SERIES HAS BEEN HELD RESPONSIBLE FOR AT LEAST 100 DEATHS IN CALIFORNIA SO FAR. IN ESSENCE, YOUNG DRUG ABUSERS WHO TAKE THESE NEW SYNTHETICS ARE PLAYING A FORM OF RUSSIAN ROULETTE. ONLY IT IS NOT LEAD BULLETS

THAT THEY ARE AIMING AT THEIR BRAINS, BUT CHEMICAL ONES.

GIVEN THIS SCENARIO, ONE WOULD PREDICT IT WAS ONLY A MATTER OF TIME BEFORE A TRUE POISON "HITS THE STREETS." THIS IS PRECISELY WHAT HAPPENED IN NORTHERN CALIFORNIA IN 1982, WHEN A HIGHLY TOXIC COMPOUND KNOWN AS MPTP WAS CIRCULATED. THIS COMPOUND IS NEUROTOXIC TO A GROUP OF CELLS IN THE BRAIN KNOWN AS THE SUBSTANTIA NIGRA. BY PURE COINCIDENCE, THIS HAPPENS TO BE THE SAME AREA THAT IS DAMAGED IN PARKINSON'S DISEASE. WE SAW A GROUP OF YOUNG ADULTS TWO YEARS AGO COME TO THE SANTA CLARA VALLEY MEDICAL CENTER WHO RESEMBLED IN EVERY WAY ELDERLY PATIENTS WITH END-STAGE PARKINSON'S DISEASE. THESE YOUNG ADDICTS HAD LITERALLY FROZEN UP OVERNIGHT, AND WERE TOTALLY UNABLE TO MOVE OR TALK. TREATMENT WITH ANTI-PARKINSONIAN THERAPY WAS PROBABLY LIFE-SAVING IN THREE; HOWEVER, THESE PATIENTS CONTINUE TO BE SEVERLY DISABLED AND REQUIRED MEDICATION EVERY ONE TO THREE HOURS JUST TO BE ABLE TO MOVE AND EAT OR DRINK. TWO OF THEM HAVE RECENTLY UNDERGONE PROLONGED HOSPITALIZATIONS, AND THE OUTLOOK FOR THEIR FUTURES MUST BE CONSIDERED GRIM INDEED.

WHILE THERE ARE CURRENTLY ONLY TWENTY SEVERELY INVOLVED YOUNG ADULTS WHO HAVE BEEN PERMANENTLY CRIPPLED BY THIS FIRST "DESIGNER DRUG DISASTER", WE HAVE NOW IDENTIFIED AN ADDITIONAL 500 PEOPLE WHO WERE EXPOSED TO MPTP THINKING IT WAS A NEW "SYNTHETIC HEROIN." MY ESTIMATE IS THAT WE HAVE JUST BEEN SCRATCHING THE SURFACE SO FAR, AND THAT THERE ARE AT LEAST ONE TO TWO HUNDRED MORE. WHY ARE THESE ADDITIONAL INDIVIDUALS IMPORTANT? BECAUSE WE NOW HAVE EVIDENCE THAT DAMAGE TO THIS AREA OF BRAIN, EVEN IF IT IS NOT ENOUGH TO CAUSE SYMPTOMS AT FIRST MAY ACT LIKE A TIME BOMB, WITH CHANGES IN THE BRAIN SLOWLY TICKING AWAY. IN OTHER WORDS, SOONER OR LATER, THESE YOUNG ADULTS COULD COME DOWN WITH A PARKINSON'S DISEASE-LIKE STATE. UP UNTIL NOW, THIS CONCERN WAS JUST THEORETICAL, BUT IN THE LAST SEVERAL MONTHS, WE HAVE STARTED SEEING A GROUP OF

YOUNG PEOPLE AT SANTA CLARA VALLEY MEDICAL CENTER WHO USED MPTP TWO YEARS AGO WHO ARE NOW STARTING TO DEVELOP A MYRIAD OF SYMPTOMS, ALL SUGGESTIVE OF EARLY PARKINSON'S DISEASE. IN SHORT, WHAT WE MAY BE FACING IS AN EPIDEMIC OF PARKINSON'S DISEASE IN YOUNG ADULTS IN NORTHERN CALIFORNIA AS A RESULT OF THIS CATASTROPHE. THE COST TO SOCIETY, NOT TO MENTION THE HUMAN SUFFERING, COULD BE IMMENSE.

I BRING THIS ENTIRE PHENOMENON TO YOUR ATTENTION FOR A NUMBER OF REASONS. FIRST, I SEE IT AS A TREMENDOUS POTENTIAL HAZARD IN TERMS OF DEALING WITH AND COMBATING THE DRUG PROBLEM AMOUNG OUR YOUTH. WAYS TO DEAL WITH THIS PHENOMENON AND HOPEFULLY SLOW OR STOP IT MUST BE STUDIED NOW. SECONDLY, THE COSTS IN TERMS OF PUBLIC HEALTH HAZARD HAVE NOW FOR THE FIRST TIME BECOME CLEAR WITH THIS FIRST "DESIGNER DRUG" DISASTER. THE PARKINSON'S CASES MAY ONLY BE THE FIRST WAVE OF DRUG ABUSE TO CROSS OVER FROM CURRENT TREATMENT MODALITIES TO FULL, LONG TERM INPATIENT OR MAINTENANCE TYPE MEDICAL CARE. THE COST OF TREATING SEVERLY AFFLICTED PATIENTS MAY SEE MEDICAL COSTS SKYROCKET TO BETWEEN $10 & $20 THOUSAND PER MONTH DEPENDING ON THE INDIVIDUAL CASE. THUS, THE MEDICAL ECONOMICS FACET OF DESIGNER DRUG USE IS ANOTHER DILEMMA THAT GOVERNMENT MUST CONFRONT.

WE NEED HELP AND ASSISTANCE IN DEALING WITH WHAT MAY BE AN ONSLAUGHT OF YOUNG PEOPLE WITH PROGRESSIVE NEURODEGENERATIVE DISEASE AS A RESULT OF THIS. FURTHER, IT SEEMS EXTREMELY IMPORTANT TO STUDY AND TRY TO UNDERSTAND THIS FIRST CATASTROPHE WITH THE IDEA OF DEVELOPING TECHNIQUES AND WAYS TO DEAL WITH FUTURE ONES WHICH ALMOST SURELY WILL OCCUR GIVEN THE POPULARITY OF THIS NEW APPROACH. WE HAVE ALREADY DISCOVERED AT LEAST ONE PATIENT WHO HAS AN ENTIRELY DIFFERENT NEUROLOGICAL SYNDROME CHARACTERIZED BY MOVEMENTS CLOSELY RESEMBLING HUNTINGTON'S CHOREA WHICH HAVE COMPLETELY DISABLED HIM. THERE ARE ALSO REPORTS

THAT THERE IS A NEW PCP "DESIGNER DRUG" WHICH IS TOXIC AS WELL. WHILE TRADITIONAL STREET DRUGS POSE A MAJOR PUBLIC HEALTH PROBLEM AND NEED TO BE DEALT WITH, I BELIEVE THIS IS AN INSTANCE WHERE ATTENTION TO A DEVELOPING AND POTENTIALLY EVEN MORE SERIOUS PHENOMENON IS FULLY WARRANTED NOW TO PREVENT A MUCH GREATER PROBLEM IN THE FUTURE.

LET ME END BY SHARING THESE THOUGHTS.

1. ECONOMIC AND SOCIAL COSTS MUST BE CONSIDERED AN IMPORTANT PART OF ALL DISCUSSIONS REGARDING SYNTHETIC DRUGS, ESPECIALLY BECAUSE OF THOSE DRUGS WHICH CAN CAUSE NEURODEGENERATIVE DISEASES SUCH AS MPTP. MANY OF THESE PATIENTS REQUIRE FREQUENT HOSPITALIZATION INCLUDING INTENSIVE CARE BECAUSE OF THE NEED TO STABILIZE THROUGH THERAPEUTIC DOSES OF MEDICATION.

   SOME OF THEM, THE MORE SEVERELY AFFECTED, WILL REQUIRE LONG TERM AND CONSTANT NURSING SUPERVISION, A MOST COSTLY ENDEAVOR. WE CANNOT ESCAPE THE IRREFUTABLE FACT THAT WE HAVE BEFORE US, A PROBLEM OF SERIOUS MEDICAL AND ECONOMIC GRAVITY. SIGNIFICANT COSTS WILL OBVIOUSLY ARISE FROM NEEDED LAW ENFORCEMENT AND TREATMENT PROGRAMS AS THE PROBLEM'S SEVERITY INTENSIFIES.

2. THE TRAINING NEEDS FOR BOTH LAW ENFORCEMENT AND THE TREATMENT NETWORK MUST BE ADDRESSED IMMEDIATELY. WITHOUT APPROPRIATE TRAINING THESE INSTITUTIONS CANNOT MITIGATE THIS EMERGING PROBLEM.

3. LABORATORIES PLAY AN ESSENTIAL ROLE IN OUR ABILITY TO DETECT THE FENTANYL ANALOGS IN BODY FLUIDS. CURRENTLY, WE HAVE ONLY ONE LABORATORY IN CALIFORNIA WITH THE EXPERTISE TO DO THIS.

8. THE LOW RISK OF DETECTION WILL STIMULATE THEIR USE IN POPULATIONS SUCH AS PRISONERS, PAROLEES, AND MILITARY PERSONNEL.

9. EASY TO SYNTHESIZE FROM COMMON INDUSTRIAL CHEMICALS.

10. PRODUCE EFFECTS IDENTICAL TO HEROIN.

11. EXTREMELY POTENT (1000 TIMES HEROIN).

12. NOT DETECTED BY ROUTINE CHEMICAL ANALYSIS.

13. NOT CLASSIFIED AS RESTRICTED (ILLEGAL) DRUGS.

14. LESS SOPHISTICATED LABORATORIES WILL ATTEMPT TO MAKE FENTANYL DERIVATIVES, THUS INCREASING THE POSSIBILITY OF TOXIC BY-PRODUCTS.

15. OTHER FAMILIES OF VERY POTENT HEROIN-LIKE DRUGS WILL BE SYNTHESIZED, APPEAR ON THE STREETS, AND BE EQUALLY AS DIFFICULT TO DETECT.

16. FAMILIES OF OTHER DRUGS OF ABUSE (COCAINE, THE HALLUCINOGENS) WILL BE SYNTHESIZED AND APPEAR ON THE STREETS.

IN SHORT, IN THE FUTURE, DRUGS OF ABUSE WILL BE SYNTHESIZED DOMESTICALLY FROM READILY AVAILABLE CHEMICALS.

To my colleagues, Gary L. Henderson, Ph.D., Associate Professor, Department of Pharmacology, U.C. Davis School of Medicine, and J. William Langston, M.D., Chief, Department of Neurology, Santa Clara Valley Medical Center, Associate Professor of Neurology, Stanford University, my thanks for their continuing contributions to this most difficult problem.

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Senator HAWKINS. Thank you, Mr. Roberton. I have some questions for you, but first we will go to Dr. MacDonald for his testimony.

Dr. MACDONALD. Thank you, Madam Chairman. I am delighted to be here this morning to discuss this significant and dangerous problem that faces us today.

With me to help respond to questions later, I have Dr. Richard Hawks, a brochemist with the National Institute on Drug Abuse, and Dr. James Rutenbur, an epidemiologist from the Centers for Disease Control, who has been working in northern California and looking at the patterns of designer drug use there.

With your permission, I will read just a brief part of my statement, paraphrase more, and summarize a lot.

Senator HAWKINS. Surely.

Dr. MACDONALD. I am going to focus on three distinct types of designer drugs and mention some of the coordinated efforts of the Public Health Service to deal with them.

Before discussing the serious adverse health consequences, I want to describe what we mean when we say "designer drugs." Mr. Roberton has led into that. Designer drugs are structually similar to substances which are already scheduled under the Controlled Substances Act, and they are designed by underground chemists to mimic the psychoactive effects of the drugs already scheduled. However, because the designer drugs are not identical in structure to the parent compounds, their manufacture and distribution are not now a violation of the Federal law. They pose significant hazards to the health and safety of Americans, not only because of the similarity to the parent compounds, and the danger of overdose, but also because of toxic impurities that they may contain. In addition, as new structures are put together, the altered chemical structure may produce toxic effects of which we are as yet unaware.

There is almost a limitless number of drugs that can be produced. In the case of fentanyl, there are at least 4,000 possible analogs which can be produced, and it does not take a genius to do it. Mr. Roberton mentioned state-of-the-art chemists, but people with considerably less than state-of-the-art knowledge and inexpensive and easily obtained materials can get into this highly profitable business.

The three classes of drugs I would like to briefly talk about are those designer drugs related to PCP, the designer drugs related to the powerful narcotics, morphine—the ones that Mr. Roberton talked primarily about, fentanyl and the meperidine derivatives—and finally, the amphetamine and methamphetamine derivatives, which are another concern.

Phencyclidine is perhaps a precursor or a prototype of the designer drug industry. NIDA was involved as early as 1978 in looking at models made from the original PCP. Three of the models were subsequently placed under schedule I of the Controlled Substance Act because of abuse. NIDA was able to make 35 PCP analogs at that time.

Fortunately, PCP analogs have not because a major public health problem, but remain possibilities for future misuse.

The fentanyl analogs, as has been said, are related to a marvelous drug, fentanyl, which is used as an anesthetic in over 70 percent of the surgical procedures in this country. It has a rapid onset of action and is relatively safe, but because of its easy modification it has produced a number of chemical analogs and their entry into the street is a source of major concern. I will cover some of the ways those modifications look using a chart and models in the discussion period later.

Fentanyl, as has been said, is 100 times stronger than heroin and some of the synthetic fentanyls are stronger yet. Like morphine, they can produce euphoria, analgesia, and addiction.

In 1979, we began having troubles with the first of these so-called synthetic heroins—alpha-methyl-fentanyl, which we believe is responsible for at least 100 deaths in this country to date. Subsequently, the drug was placed under schedule I in 1981. Then a new fentanyl analog emerged of great concern to us. This drug 3-methyl-fentanyl, is also illustrated on the board.

In the San Francisco area where the 3-methyl-fentanyl derivatives were first introduced, they are definitely still present and continue to be sold in the illicit market. Deaths have also occurred in other States, most recently, a related death in Broward County, as well as in Arizona and Oregon. The epidemic which at one time we thought was pretty much contained in California, seems to have spread.

The second-class analogs are related to Demerol, a widely used and legal painkiller. They seem to emerge when heroin becomes scarce on the street. Two drugs, MPPP and PEPAP, were both scheduled under the emergency scheduling authority earlier this month. Problems have occurred not only because of the potency of MPPP but also because of the toxicity of a byproduct chemical, MPTP, which was covered in Mr. Roberson's television presentation.

These drugs have no medical use and are obviously a serious concern. The abuse of MPPP was first reported in Washington, DC, in 1976, associated with a case of Parkinson's disease caused by MPTP and was studied by the National Institute of Mental Health.

This trail led investigators—principal among whom was William Langston, who was in the movie—to the discovery that indeed it was this chemical, MPTP, that was causing the Parkinson's disease. Ironically, a favorable side effect of that disaster was that MPTP has become the first drug which we can now use to produce an animal model of Parkinson's disease, a disease that affects over 500,000 Americans today.

Since 1976, this drug has continued to distributed on the streets. Investigators from CDC have been following this drug's usage patterns, and we are convinced that there is still a problem with the MPTP in this country. PEPAP has also been identified in conflications in California and Texas.

The last group I would like to talk about are the amphetamines and methamphetamine analogs, both legal drugs with stimulant properties, but with chemical alteration, their analogs develop properties of hallucinagenic drugs. The one that is perhaps the current media favorite is one called Ectasy or MDMA. This drug is similar in most ways to MDA, which we know has toxic side effects

directly on the center of the brain where serotonin is produced. MDMA is like MDA in structure. It produces a similar high, with altered consciousness, change in sense of acoustics and visual and tactile feelings, and mild intoxication. It is easy to make. It has become popular among college students and has been used by some psychotherapists.

The serotonergic system that is affected is the one that is involved with sleep, mood regulation and sexual activity and sensivitity to adverse stimuli—a very important area of the brain. Because of our concern that this chemical so closely relates to another that is shown to have those properties, MDMA was placed on the emergency scheduling list in July 1985.

The Public Health Service has been involved in many ways in addressing the problems of designer drugs and I would like to just summarize four general areas. First, the Office of the Assistant Secretary for Health has been acting to coordinate our efforts. Second, we have been looking at the epidemiology, that is how much of this is going on, and where it is located and what are its effects. Third, we have been doing research on the drugs themselves—what are their toxic effects; what are their abuse potential; what are their pharmacology. The National Institute on Drug Abuse has a contract to prepare these drugs for researchers and for the DEA to use them in their labs. And finally, and perhaps as important as the rest, we have had an ongoing campaign to advertise to physicians, drug users, and to the public the dangers of these drugs.

In summary, we do have a serious health problem which relates to these easily produced drugs, and the Public Health Service remains concerned about the problem of dealing with drugs under the current legislation which seems to be inadequate in responding to the designer drug problem.

I will be willing to answer questions. I have asked that Dr. Hawks and Dr. Rutenber join me.

Senator HAWKINS. Surely. Thank you.

[The prepared statement of Dr. MacDonald follows:]

STATEMENT OF DONALD IAN MACDONALD, ADMINISTRATOR, ALCOHOL DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Madame Chairman and Members of the Committee:

I am Dr. Donald Ian Macdonald, Administrator of the Alcohol Drug Abuse and Mental Health Administration, and I am pleased to be here this morning to discuss the designer drug problem in America. My remarks will concentrate on three distinct types of designer drugs and the coordinated efforts of the Public Health Service (PHS) to curb their abuse.

Before discussing the serious adverse health consequences of these substances, let me describe what we mean when we refer to designer drugs. Designer drugs are structurally similar to substances already scheduled under the Controlled Substances Act (CSA), and are designed by underground chemists to mimic the psychoactive effects of the drugs already scheduled. However, because designer drugs are not structurally identical to parent compounds, their manufacture and distribution are not now a violation of that Federal law. These substances pose significant hazards to the health and safety of Americans not only because of their similarity to parent compounds, and the consequent danger of overdose, but also because they may contain toxic impurities. In addition, designer drugs can present other problems because their altered chemical structure may produce toxic effects not observed in the parent compound.

The number of designer drugs that potentially can be made and distributed is very large, since virtually anyone with a background in college chemistry can obtain the

information necessary to synthesize them. At present, there are three major types of designer drugs available through the illicit drug market in this country. These include the analogs of phencyclidine (PCP); the analogs of fentanyl and meperidine, both powerful narcotic analgesics, and the analogs of amphetamine and methamphetamine, which have hallucinogenic properties. Street names of these drugs, such as "synthetic heroin," "China White," and "new heroin," are often used interchangeably to designate a wide variety of drugs. This morning I will discuss what we know about the these substances and what we have done to curb their use.

Phencyclidine Analogs

The manufacture and distribution of phencyclidine (PCP) analogs is a possible prototype for the designer drug problem we now face. While PCP was originally developed in the 1950's as an anesthetic for human use, its side effects, including hallucinations, gradually caused the manufacturer to limit its use to veterinary purposes. Even this approved use stopped in 1978 when the manufacturer halted commercial production as a result of more restrictive controls imposed under the CSA. Although PCP itself is now controlled in Schedule I of the CSA, over 35 analogs of PCP have been synthesized by the National Institute on Drug Abuse (NIDA). Most of these analogs have been tested to determine their abuse liability or pharmacologic properties. Three of these analogs were subsequently placed in Schedule I of the CSA after abuse of them became widespread. Since then, however, other PCP analogs have not presented problems even though they are relatively easy to synthesize.

Fentanyl Analogs

Fentanyl is used for analgesia in over 70 percent of the surgical procedures performed in the United States. Its medical popularity is derived from its rapid onset of action and its therapeutic efficacy and safety. Many hundreds of fentanyl analogs could theoretically be prepared from commonly available starting materials, and most of these substances would likely have pharmacological properties similar to heroin or morphine. The fentanyl analogs are generally hundreds of times more potent than morphine or heroin. They produce euphoria, are strong analgesics, and create addiction by acting through the opiate receptor. Several fentanyl analogs which mimic the action of heroin have been produced and sold on the street as "synthetic heroin." In 1979 the fentanyl analog, alpha-methylfentanyl, became widely available in California, and since then this substance and the other fentanyl analogs are believed to be responsible for numerous hospital emergency room visits and has caused over 100 overdose deaths. Additional evidence of the pervasive use of fentanyl analogs comes from routine urineanalysis tests of methadone clinic patients in the Los Angeles area. Recent estimates by California health officials suggest that up to 20 percent of these patients may be users of fentanyl or one of its analogs.

Because of the problems it created, alpha-methylfentanyl was placed in Schedule I of the CSA on September 22, 1981. Since the control of alpha-methylfentanyl, law enforcement laboratories have identified other fentanyl analogs clandestinely produced and distributed in California. Available information did not indicate that these analogs were causing a

widespread public health and safety hazard until 1984. Increased reports of the distribution, abuse, and health hazards of the fentanyl analogs coincided with the identification of 3-methylfentanyl in samples from the San Francisco bay area by laboratories of the Drug Enforcement Administration (DEA) in late 1983 and 1984. By 1985, 3-methylfentanyl had been detected in 41 samples, all but one of which originated in the San Francisco Bay area. The lone exception was from a sample obtained in Brooklyn, New York in July, 1984. Other recent anecdotal information suggests that the analogs of fentanyl have caused one death each in Arizona and Oregon.

Meperidine Analogs

Meperidine, better known by its common trade name "Demerol," is a narcotic used to control severe pain. Over the past decade, we have seen the illicit use of meperidine periodically increase when supplies of heroin become scarce. Lately, designer drugs with pharmacological effects similar to heroin have been found to be similar in structure to meperidine, which is controlled in Schedule II of the CSA. Two such analogs; 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenylethyl)-4-acetyloxypiperidine (PEPAP) have appeared on the street. In tests measuring the analgesic potency of MPPP, the substance was found to be several times more potent than morphine. Toxicity studies using subcutaneous administration of MPPP in mice yielded a lethal dose for one-half of the mice tested at 40 mg per kg of body weight compared to 196 mg per kg of body weight for meperidine. The analgesic potency of PEPAP, as measured after subcutaneous administration in mice and rats, ranged from

12 to 72 times that of meperidine. Neither MPPP nor PEPAP have any legitimate medical use or manufacture in the United States. And, while both of these substances present significant risks to those misusing them, impurities formed during the clandestine manufacture of MPPP are causing particularly unfortunate and irreversible consequences.

The abuse of MPPP was first reported in the Washington, DC area in 1976 when a 23 year old man was referred to the National Institute on Mental Health (NIMH) for evaluation after exhibiting symptoms of Parkinson's Disease. A known drug user, he had used the meperidine analogue MPPP which he himself had manufactured. This individual reported that intravenous and intramuscular use of MPPP produced an opiate-like high and other subjective effects similar to those of meperidine. Since he was able to provide the chemical formula and procedures he had followed to produce the MPPP, it was discovered, through subsequent analysis, that he had inadvertently created the substance MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine). The critical insight linking MPTP to the Parkinsonian syndrome was provided by Dr. J. William Langston, a grantee of the National Institutes of Health, whose studies showed that MPTP was responsible for producing the Parkinsonian syndrome.

Since 1976, numerous samples of clandestinely produced MPPP that contain MPTP have been identified. Several examples of MPPP were analyzed in 1982 from samples taken from the San Francisco Bay area, each contained the neurotoxin MPTP. Some of the MPTP-containing samples had been obtained from individuals who were hospitalized with a Parkinsonian syndrome. Seven victims of MPTP-induced Parkinsonian symptoms continued under treatment in 1983 in the same area of California.

Their Parkinsonian syndrome appears to be chronic and irreversible, but can be treated with the drug L-dopa. The victims of MPTP-induced Parkinson's, however, will require long-term care and medication. Individuals exposed to MPTP whom may not now show Parkinsonian symptoms are certainly at risk for developing the syndrome at some point later in life. This is because the neurotoxic damage has already occurred and the effect is unmasked by the aging process. Consequently, early identification and diagnosis is needed if these persons are to avoid the adverse consequences of misdiagnosis, which complicated the lives of several persons now under treatment for an MPTP-induced Parkinsonian syndrome.

PEPAP, (1-(2-phenylethyl)-4-Phenyl-4-acetyloxypiperidine), is a recent addition to the street scene, having been identified by the DEA in confiscations this year in California and Texas. Its action is substantially similar to that of MPPP.

Amphetamine And Methamphetamine Analogs

Several dozen analogs of amphetamine and methamphetamine are known, or theoretically likely, to be hallucinogenic drugs. Some have appeared on the street and have been Scheduled under the CSA in the past, but others have not. One example of an analogue of methamphetamine which currently poses a threat to the health and safety of Americans is 3,4-methylenedioxymethamphetamine, or MDMA. MDMA and its parent compound MDA, produce similar psychopharmacological effects including altered consciousness, increased acoustic, visual and tactile sensory perceptions, and mild intoxication.

MDMA was first identified in the illicit drug traffic and analyzed by DEA laboratories in 1970. Since that time it has been encountered 24 times by DEA laboratories and reported by forensic laboratories in 8 States. It has also been routinely reported by Pharm Chem Laboratory, an independent laboratory analysis firm, since 1976.

The synthesis of MDMA is analogous to that of MDA, requires no elaborate apparatus or sophisticated techniques and can be made from readily available materials. Recently, MDMA has received considerable attention from the media, which have reported that MDMA (or "Ecstasy," as it is known on the street) is widely used as a legal euphoriant among college students and by some physicians as an adjunct to psychotherapy. This unapproved, so-called therapeutic use of MDMA by physicians, as well as its clandestine production, continues in many sections of the country.

The adverse health effects of amphetamines such as MDA have been known for years. One recent survey of relevant research shows that a single dose of MDA can selectively destroy serotonergic nerve terminals in the rat brain. The serotonergic system, which is also present in man, plays a role in regulating sleep, mood, sexual activity, and sensitivity to aversive stimuli. This type of evidence leads experts to conclude that because of the neurotoxic effects of compounds structurally similar to MDMA, (e.g., MDA, amphetamine, and methamphetamine) and because both MDMA and MDA cause the release of endogenous serotonin, it is likely that MDMA will produce neurotoxic effects similar to those of MDA. Because of these similarities, an effort to place MDMA in Schedule I of the CSA was initiated on July 27, 1984. After receiving new reports of its widespread abuse and possible neurotoxicity, DEA hastened the

scheduling process by placing MDMA into Schedule I on an emergency basis.

Federal Response

In order to respond adequately to the designer drug problem, Federal law enforcement and health agencies have taken positive steps over the past several years. The overall response to the problem involves actions taken by the Department of Justice, chiefly the Drug Enforcement Administration, and several agencies of the Public Health Service in the Department of Health and Human Services. I would like to describe what has been accomplished by the agencies of the Public Health Service.

As you know, the Public Health Service conducts health research programs and provides information and technical assistance to States on numerous health-related problems. PHS efforts have been important in understanding the designer drug problem, and I would like to highlight specifically actions taken by the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) and the Centers for Disease Control (CDC).

One of the most important contributions of the PHS was the early identification of MPTP and the development of the animal model for Parkinson's disease. These scientific findings not only illuminated the dangers of clandestinely produced drugs, but also provided researchers investigating Parkinson's Disease with a long-needed animal model of the disease's process. Since 1976, numerous PHS sponsored research studies have begun to examine the process by which brain cells are selectively attacked and destroyed by MPTP and other substances. Recently, the Public Health Service sponsored a two-day

symposium on MPTP in Bethesda, Maryland during which scientists from several countries presented findings on the toxicity, clinical pathology, and epidemiology of MPTP.

Other research into MPTP, and designer drugs in general, has been initiated. Investigations of the nature and extent of MPTP use in California and now other parts of the nation have been conducted by the CDC and NIDA. In January, 1985, CDC and NIDA began to interview and locate persons who may have been exposed to MPPP and MPTP. The study found that since 1982 approximately 50 persons have reported the use of a substance which produced symptoms similar to those reported by known users of MPPP/MPTP. Preliminary results from the study, conducted at the request of the State of California, suggest that over 400 persons may have been exposed to MPTP in California. During the field investigation, 173 persons that reported they had experienced symptoms similar to those reported by known users of the drug. To date, 83 of these persons received a complete evaluation, consisting of a lifetime drug history, a report of the signs and symptoms indicative of the early stages of the Parkinsonian syndrome and a brief neurologic examination. Ongoing field studies of the extent of MPTP use and its severe adverse health consequences are currently being undertaken by these agencies to determine if the MPTP-induced Parkinsonian syndrome has spread to other locations in the United States.

PHS activities have not been limited to research. NIDA notified the drug abuse treatment and prevention community nationwide of the dangers of MPTP. Together with the National Institute on Mental Health (NIMH), NIDA prepared a report on MPTP for publication in the Morbidity and Mortality Weekly Report (MMWR), the CDC publication

which reaches a national audience of physicians. This report served as the basis for an article later published in the Journal of the American Association which reached an even wider audience. The July, 1985 issue of NIDA's "Clinical Research Notes" will contain an article summarizing recent findings about the possible neurotoxicity of MDMA.

At the same time, NIDA continues to support research projects seeking to understand basic mechanisms of action in designer drugs. In order to provide designer drugs to researchers for this purpose, NIDA maintains the ability to synthesize compounds and distribute them to research laboratories for chemical and pharmacologic evaluation. Recently, NIDA has produced large quantities of MDMA in order to study its abuse liability in animal models. In June, the production of 3-methylfentanyl was carried out by NIDA to provide DEA with an authentic sample of this recently controlled substance. Several other analogs are also being prepared.

Data on the extent of abuse and the adverse health consequences of drugs are needed to schedule substances under the CSA. The designer drugs, however, are extremely difficult to track through existing drug abuse data systems operated by NIDA. Not only are the substances so closely related chemically to a parent compound thus creating identification problems, but as in the case of the fentanyl analogs, toxic doses are often so small they are easily overlooked by routine laboratory analysis. As a result, data collected from hospital emergency rooms and medical examiners across the nation and reported to NIDA's Drug Abuse Warning Network do not provide a valid measure of the designer drug problem in this country. We do have other means of gathering these data, however,

including special epidemiologic studies, such as the NIDA-CDC collaborative project mentioned earlier, and NIDA's Community Epidemiology Work Group (CEWG). In its most recent semi-annual meeting held in June, 1985, CEWG members reported that the fentanyl compounds continue to be a severe problem in southern California. In San Diego, 24 fentanyl related deaths have been reported since mid-1982, with 10 deaths occurring during 1984 and four more deaths so far this year. Indications that fentanyl analogs are available in other areas of the country, including New York and Atlanta, were also noted. Several preliminary reports from the CEWG also suggest that meperidine analogs may have become available in other parts of the country outside California.

Efforts of FHS agencies to further understand the health implications of the designer drug problem will continue to focus on epidemiologic studies, research investigat ons, synthesis and distribution of compounds, and knowledge dissemination activities.

Before closing my remarks, I would like to stress that designer drugs do present a serious hazard to those who use them, but that the use of these substances has so far been confined to relatively few areas of the country. As of now, the designer drugs I have discussed this morning certainly have not begun to present problems as widespread as marijuana, cocaine, or heroin. Nevertheless, many of these drugs lack any known health benefit and indeed are causing very severe adverse health consequences. Consequently, we must exercise our options to control these substances, including the emergency scheduling authority which can be used to place them under the CSA.

Because current laws are not adequate to address the unique problems of designer drug manufacture and distribution, PHS staff worked with the DEA to formulate the legislation which is the subject of this hearing. In developing this proposal, we were careful to avoid inhibiting research or interfering with the legitimate manufacture of drugs, by exempting individuals or companies which apply for and receive appropriate FDA approval to develop a new drug. We believe this legislation will attack the designer drug problem at its source, and we hope that Congress will enact this control which is necessary if we are to be more successful in halting the abuse of these dangerous drugs.

Madame Chairman, this concludes my statement, and I will be pleased to answer any questions you may have.

Senator HAWKINS. Mr. Roberton, you mentioned the lack of laboratories, and the hindrance of the Government's efforts to assess the nature and magnitude of the synthetic drug problem. You say there are only two laboratories?

Mr. ROBERTON. To my knowledge, there are only two labs that you can send samples to. One is to the University of California at Davis, and the other one is to the Drug Enforcement Administration lab. This is biological fluids and powder samples that are from drug treatment programs.

Senator HAWKINS. So you would recommend that we have more?

Mr. ROBERTON. I think that we need a network. I do not think the synthetic drug game is over. I think that it is not just the State of California, or one or two States. I think labs need the ability to be able to test the levels of these drugs. So, yes, we do need more.

Senator HAWKINS. And you alluded to the fact that it is a big problem in California, and as goes California, so goes the nation. Do you have any idea of how large a national problem this is as opposed to a local problem?

Mr. ROBERTON. I do not, Madam Chairman. One hears of the synthetics spreading to other States. There have certainly been deaths in Oregon and Arizona. I knew of no other areas, until Dr. MacDonald talked about Broward County, in fact.

Senator HAWKINS. The Fort Lauderdale area.

Mr. ROBERTON. And we have heard in Fort Lauderdale and in New York, yes.

Senator HAWKINS. I believe they demolished a lab in Texas, also. The drug enforcement agents will talk about that, but that gives it some Southern distribution, too.

What should the Government focus on initially as we address this growing problem?

Mr. ROBERTON. Well, let me answer it this way. The State of California has been supporting part of the lab at the University of California at Davis to come up with a test that all labs could use; we could just give it away. And after 4 years, we are unable to have that simple test.

I would like to see the Government look into the area of working more towards a solution to this problem in terms of laboratories. I think that is very, very important that other labs out there, commercial labs, do have the ability to detect fentanyl in urine and blood.

Senator HAWKINS. In your opinion, do the majority of users consciously buy these synthetics, or do they think they are buying the "real thing?"

Mr. ROBERTON. I would say that about 70 percent believe that they are buying heroin. In some counties in California now, addicts are beginning to ask for "that synthetic stuff". Some of them subjectively think it is less adultered; they get a better high. I am not sure whether that is true or not, though it has the same actions of heroin. But I would say about 70 percent do not know they are getting synthetic heroin.

Senator HAWKINS. I noticed from your movie, which was condensed for us here today—it is an excellent film, by the way—do you find in your research that this is confined to any age group—young——

Mr. ROBERTON. We have had in California an increase of about 20 percent of 17-year-olds using heroin. If they are buying heroin on the street, then I have to assume that 20 percent of them must be also using the fentanyl series. And we have clients in our treatment programs between the ages of 16 and 60 that are heroin users. So I would imagine it is spread throughout the general population.

Senator HAWKINS. I noticed, in the film, you used the family series. We discovered this situation in a hearing in Miami a year or two ago, when drug control officials told us of this new phenomenon in which the mother gets the children to take drugs with her. Are you seeing that in California?

Mr. ROBERTON. I have seen that for the last few years, Madam Chairman. That is not a new phenomenon in terms of families who are using heroin together. That has been going on for some time.

Senator HAWKINS. You do hear the usual, that as well, is that the families are upset, because their children started using drugs.

Mr. ROBERTON. Yes; but you do have whole families that do use. In all the years that I have been in "the drug business", that has occurred, where you have mom and dad, and then the children.

Senator HAWKINS. I know users of heroin pass on their addiction to the unborn. Does this happen also with synthetic drugs?

Mr. ROBERTON. It is identical in its actions, Madam Chairman. I think Dr. Hawks can answer that better than I can, but my understanding is it is identical in action.

Senator HAWKINS. And how do we handle that—anyone on this medical panel—how do we handle that new baby who is born addicted?

Mr. ROBERTON. They are getting the same treatment in Los Angeles, I know, as in other areas—in San Francisco, in Contra Costa County, the children of addicted mothers are being treated the same; the neonates are being treated the same as they would if they were addicted to heroin.

Senator HAWKINS. In your opinion, then, we are facing a new and a costly dilemma involving the medical treatment of synthetic drug users, because these drugs cause Parkinson's disease. Most of the people on the film looked older, but as you described synthetic narcotics to us, its use ages the body rapidly. So they could be younger people——

Mr. ROBERTON. Certainly, with the MPTP, there were some very young people. They do not look in their twenties now; they look older.

Dr. Rutenber, who has seen many patients as well in California when he came from CDC—they are not necessarily older people.

Senator HAWKINS. Could you speak to that, Dr. Rutenber?

Dr. RUTENBER. Actually a group of people who have not received a lot of publicity, but whom we are quite worried about, are children who are born to mothers who were taking MPTP when they were pregnant. We have identified around 10 children who have been exposed in this manner. We have no idea what is going to happen to them neurologically, but we think there is going to be a danger. In general, most of the drug abusers that we have worked with are in their late twenties and thirties, the ones that have been exposed to the Demerol analogs that contain the neurotoxins.

Senator HAWKINS. I know it eventually leads to death, but how long is their lifespan when they have Parkinson's disease? Some looked more advanced than others. How long will society have to care for these people?

Dr. Rutenber. Well, this is something we really do not know now, and this is why it is very important for us to support the following of a group of people we have identified in California. We are not certain that the Parkinsonism that is caused by MPTP is identical to what is called ideopathic Parkinsonism, the kind of Parkinsonism that our older citizens get. It is important to determine exactly what form this disease will take. If it is similar to ideopathic Parkinsonism, we can predict that they will probably have almost a normal lifespan in terms of living out their lives, except for the patients that are in the very severe stages. We have seven or eight patients now who are at end stage for Parkinsonism, and they probably will not have a lifespan beyond 10 years from now.

The other people that we are quite worried about, though, are these people who have very slight symptoms now. We do not know whether they are going to progress or not. And it may be that in 10 years, they will look like some of the patients you saw in the movie.

Senator HAWKINS. Mr. Roberton, to your knowledge, has law enforcement been successful in locating and prosecuting the illicit manufacturers of the fentanyl derivative?

Mr. ROBERTON. I think in California, certainly in one case, they apprehended both chemists and materials that could have been used to make 3-methyl-fentanyl. Outside of California, I could not say.

It is a very difficult problem for the drug enforcement, because again of size of material and again, the problem of analysis. I think the DEA labs can analyze street samples, powders, very well. I am not sure when it comes to biological fluids if they can, although they do not get into that quite so much.

I think, like all drugs, it is a real problem for them. I cannot honestly say that they have done a tremendous, wonderful job in the whole area of synthetic drugs, but also, one has to see the problems associated with this in terms, as I said earlier, somebody could make a batch, close up shop, and disappear and just let a little out on the street at a time, from various areas, as opposed to a lab that is continually producing something.

There are so many ways you can look at this phenomenon.

Senator HAWKINS. Have the education efforts that your State and you particularly have been involved in proved effective?

Mr. ROBERTON. It is a little early to tell. We have mounted a campaign of education for those addicts that are already using, such as the movies shown in all the clinics, through CDC and the Santa Clara Valley Medical Center, where they will test street samples for addicts who have material they want tested anonymously, through literature, through lectures, through discussions. That is the thing we have done up until now, and I am not sure about the outcome yet, because it is early days.

Senator HAWKINS. Do you concentrate on teenagers?

Mr. ROBERTON. Well, one of the things we are concentrating on now is some of those—we believe that teenagers are too late. We

have prevention now in programs of 5- and 6-year-olds. There is one in particular, called the IALAC Program—"I am Lovable and Capable"—which seems to be very effective. So ours is a big prevention effort.

Also, the National Institute on Drug Abuse—and I am sure Dr. MacDonald can comment on this—has a "Say No" campaign. And I think together, there are big efforts. I think we need to do more of this.

Senator HAWKINS. So much of the information seems to be new to the public. As usual, I guess the kids know more about it than the grownups.

Dr. MacDonald, you said in your testimory that even college kids can make these synthetic drugs. Can you tell us more about that, without causing a campus outbreak?

Dr. MACDONALD. My comment was that they were popular with college people, particularly one of the newer drugs, MDMA, "Ecstasy," which is fairly easily prepared.

Dr. Hawks, who is with me, is a chemist, and I will have him run through some of the transformation models for Senator Hawkins.

Dr. HAWKS. OK. Madam Chairman, I will speak to the question about ease of synthesis. I think Mr. Roberton mentioned that there is a suspicion there might be a genius phantom chemist out there somewhere. I would say that our experience with synthesizing some of these materials, using our contractor at the Research Triangle Institute in North Carolina, is that they were able to use B.S. chemist technicians to synthesize most of these compounds. Some of the technicians do get supervision. Our feeling is that the possibility of synthesis of some of these compounds by people even with, say, a B.S. in chemistry, is very real. Somebody at that level of experience could make most of these fentanyl analogs we are talking about—though not all of them. The 3-methy-fentanyl is one case in point. We have illustrated it on the chart here, the second one down on the right. That one is harder to synthesize, and that has been our direct experience at RTI, than for instance the alpha-methyl-fentanyl below it or the fentanyl itself above it.

It indicates that someone in California does have more experience than the average B.S. chemist, so if someone out there can make that one, then he can make a much larger series of fentanyls.

But the fact is, it does not take a great deal of experience to put these things together.

We also have some three-dimensional models here. This one is identical to fentanyl on top, as far as chemical models go. And basically, the molecule is made up of three component parts. There is this part—I will not go into the specific names—and there is this part, and this part.

Now, these three basic components are at least one of the classical syntheses of fentanyl. All of these are readily available. They are readily available in numerous modifications—that means that you could buy this compound from a drug supply house like it is; you could buy it with a couple of methyl groups on it, or 3-methyl groups, or ethyl groups, and so on and so forth. Each of those, after you put it together with these other two, would give you several different components. So that is why there are hundreds of possi-

bilities, at least theoretically, of compounds that can be made from readily available materials, many of which can be handled by the B.S. chemist. I think that is one point.

The other point I would like to make, that is related to this in terms of how the underground chemist operates, is that there are two problems associated with quality control, which Mr. Roberton also alluded to. These are the purity of the final product and the way the dosage form is prepared. The underground chemists are not too worried about how pure and how good a quality their material is, just so it sells. So you have many possibilities of parent compounds, and you have many possibilities of side products being produced from them if you are not careful to purify them. MPTP is just one of these possible side products. So you have many possibilities of as yet unknown things being injected into or ingested by people with various levels of toxicity.

That is one problem. The other problem is death by overdose. When you are dealing with compounds that are hundreds of times more potent than what most street chemists are used to, like heroin, you have a real problem in taking 1 gram, one part of a teaspoon of powder, and mixing it with 10 or 20 pounds of filler, whatever the filler is that is going to be used for the final material, and mixing that in a homogeneous way, so that the 1 dose out of the 50,000 is the same as the other doses out of the 50,000. It is very hard to mix these things up. It is a technical problem that you do not have with heroin itself, where you are not cutting it nearly so much, and you can weigh it out in small balances that you can keep in your home.

So the possibility of a nonhomogeneous mixture and the fact that one person's dose may be an overdose, and the other person who gets it out of the same batch could be an ineffctive dose is much more a problem with these super-high-potency compounds.

I think I will stop at that.

Senator HAWKINS. We call that chemical roulette—and I have heard that from the students.

Dr. HAWKS. Yes.

Senator HAWKINS. This is a medical panel. The next panel will be comprised of consumers of these drugs. But in your opinion, is use of synthetic drugs of epidemic proportions large enough to require immediate attention, immediate action, immediate laws, and immediate coordination of all enforcement agencies, along with the scientific agencies, of the United States?

Dr. MACDONALD. I think the answer to that is clearly yes, that unfortunately, we are talking in terms of hundreds of deaths now and 400 or 500 that may have been exposed to MPTP and somewhere down the road develop Parkinson's disease. And we mentioned 10 intrauterine exposures. Those are relatively small numbers, but if this designer drug business is allowed to continue, we have reason to fear that California will not contain it, and the comments about Arizona and Texas and Florida and Oregon and British Columbia sugget that indeed it will spread.

Senator HAWKINS. I appreciate all of your participation and your expertise, and I will look forward to working with you closely on the solution to this growing problem. I know Dr. MacDonald has an

appointment, and must go. We thank you all for participating in this hearing and we excuse you at this time.

Our second panel today will examine the effect of synthetic drugs on individuals. Dr. David Nurco, our good friend who has been so helpful with this subcommittee in our research in this field, is nationally renowed in the field of drug abuse. He is accompanied by two individuals who are self-acknowledged heroin addicts, and who admit to familiarity with synthetic drugs.

We thank you very much for participating in this important forum, and our witnesses, who will accompany Dr. Nurco, have asked to be identified as "William" and "Vincent."

Dr. Nurco, you are looking well. Could you make some opening statements, please?

STATEMENT OF DR. DAVID N. NURCO, DEPARTMENT OF PSYCHIATRY, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE, ACCOMPANIED BY WILLIAM AND VINCENT, BALTIMORE, MD

Dr. NURCO. I thank you for having me here today. We have been very much concerned over in the Baltimore area.

Senator HAWKINS. Excuse me just a moment. The microphone does not seem to be working too well, and we must have quiet in the back of the room. Maybe you should close the door, Officer.

Dr. Nurco, Senator Chiles is in the other room on the telephone, but we will continue with your statement, and as he is in the middle of another hearing, we will also let him interrupt you, if you do not mind.

Dr. NURCO. Surely.

Senator HAWKINS. In fact, here is Senator Chiles.

Welcome.

Senator CHILES. Madam Chairman, I appreciate your allowing me to interrupt here a minute. I just wanted to come by and tell you that I am glad you are holding this hearing. I think the subject matter which we are talking about is one that could be one of the most dangerous things that could ever—or, we know it is already here, but it could be a scourge of our country.

I think we are dealing with what is sort of a future drug, or future drugs, and we have all seen a lot of the science fiction movies of some of the problems that are created by some of the new technology that we have. This is in a way like one of those science fiction horror stories to me, the potential of what we are talking about here.

One of the witnesses last week gave me this little vial, and it is interesting—I have to put on my glasses to see the speck that is in the bottom of that—but if you will look into that, you will see that the speck that is in the bottom of that, which is a derivative, of course, or one of these analogs of what would be. It is 7,000 times more powerful than heroin, and we see that that is not a single dose; that is multiple doses of what could happen. And I think trying to inform America of what the tremendous dangers are and trying to see that we change the laws and to get the laws on the books before this grows from California to the rest of the Nation, as we have seen in many other times, is something that all of us

have to be concerned about. So I am delighted to see your concern in this, and I hope that we can do something about it.

Senator HAWKINS. I compliment you for your leadership in this field and look forward to working with you in finding the solution to the problem of synthetic drugs. We saw a tape earlier, which I will be happy to share with you, that is being used now in California. It is very effective, and would be very good for us to have nationwide. We appreciate your taking time from your other hearing to join us.

Senator CHILES. I thank you.

Senator HAWKINS. Dr. David Nurco, we will now have a statement from you, good friend.

Dr. NURCO. Yes, Senator. We in the Baltimore area have been very concerned about drug abuse in general, but are very fearful of the designer-type drugs, particularly because most of the consumers are buying from the street, where the preparation of drugs for sale in quite poor. Unfortunately, drug abusers are buying illicit substances, mixed with cutting agents that may be harmful to them.

In the 1950's, heroin was often cut with quinine and some milk sugar and sold to drug abusers. But during the sixties and later into the seventies, additional cutting agents or diluents were introduced. Drug dealers not only used substances like Nestles Quik, but strychnine as well. In some cases, dealers may have wanted to kill a narcotic addict who was considered unreliable. Oftentimes this occurred when it was thought he talked to the police—in the language of the street it was called giving hot shots; addicts were buying drugs without knowing or often caring what they were getting. When the purity of heroin drops to 1 to 3 percent, as it often does, diluents are frequently added indiscriminately, thus greatly endangering users.

In summary, we have a rather large population of narcotics addicts and other drug abusers who are very much at risk to getting substances like designer drugs. This is a serious problem for two reasons. First, many of the addicts who use designer drugs may experience serious health problems and possibly death; and second, society will have to pay for the extensive health care requirements.

The two gentlemen accompanying us today, William and Vincent, are narcotic users and both were very much impressed by the prior testimony and with the film. In the area of drug abuse, they are quite realistic and not easily impressed. In their judgment the presentation to this committee was excellent.

I appreciate the interest of the committee and the opportunity to offer a statement and would like now to introduce two narcotic addicts from Baltimore.

Senator Hawkins, William is on my immediate left and sitting next to him is Vincent.

Senator HAWKINS. William, do you have a statement?

WILLIAM. Yes. I was very impressed with what the doctors said before about calling them designer drugs. It kind of lends credence to using drugs.

In Baltimore, we have gotten a sample of some really hot drugs, really good stuff, and evidently, it has turned out to be these designer drugs. I personally have not seen any physical problems, but

as the doctor—who just testifed—said, one dose could do it. I, personally, have used it maybe 20 or 30 times, which is really food for thought after this movie and the information that the doctors gave.

I think legislation in this field is very important. But my personal feelings are that some kind of educational program for the young is a lot more important and money better spent. Most of the dealers in Baltimore are in the age range between 9 and 16.

Senator HAWKINS. The dealers are between 9 and 16?

WILLIAM. Nine and sixteen. Prosecution there is part of the deal—not that they can't prosecute, but the legal ramifications are less for an adolescent than they are for an adult.

Senator HAWKINS. I know "hot" drugs means something to a user, so we would not want to call it a "hot" drug.

WILLIAM. Yes; "good."

Senator HAWKINS. "Synthetic" to me even sounds like "same as," maybe even implies that the drug is cheaper. Do you have any term to suggest to this committee to mull over? If so, you could get in touch with us through Dr. Nurco, our good friend and constant consultant, to let us know. I think it could help in putting out an alarm. I do not like the term designer drugs—it makes people think they should have a certain name on their tennis shoes, a certain name on the back of their jeans, and that this is something to be desired. "Synthetic" has another meaning to me, a meaning that I do not know would have much appeal to a 9-year-old or to a teenager. "Hot" drugs seems to mean it would bring a real high to those who use it.

What could we call it? This chart even says "designer drugs." But what term would you recommend that might make you stop and think that synthetic drugs are something to be afraid of?

WILLIAM. Well, the problem is that fear in the heart of a drug addict is not through terminology or even through obvious death. A true, full-blown drug addict would follow a morgue wagon to its origin of overdose to obtain that substance.

So I think putting a name on it is not the answer.

Senator HAWKINS. But you were impressed when you saw that if you got a dose of this type——

WILLIAM. Very much so.

Senator HAWKINS [continuing]. So much more potent—that you might contract Parkinson's disease, and experience premature aging, both irreversible conditions. That is not really experiencing a new high, that's killing yourself.

Why don't you think about that for a while, and keep in touch with us and let us know? I think it is very important what we call this new class of narcotic, after this hearing today. The legislation recently introduced to increase criminal penalties for synthetic drug involvement and which is called the "designer drug bill of 1985" will be referred to the Judiciary Committee, where it will surely get publicity. For this and other reasons I am sure we are going to see the term "designer drugs" again and again. I think it's dangerous. I don't like "synthetic," either. It is better than "designer," but this country has become used to "synthetic fabrics," which in many instances indicates ease of handling. Maybe it carries a different meaning generally, as the scientific use of a term is

always different than that in popular usage. I think it would be helpful to have the man on the street have some input on this.

Could you describe, William, any experiences you have had with synthetic heroin? I believe you said you have used it several times.

WILLIAM. Well, in terms of the quantity that you have to use, let's say a drug addict uses a $55 bag of heroin a day. The heroin on the street now in Baltimore has gotten to the point where a person who uses that much could in fact cut that in half, which actually is saying that the quality is improved, which is what people are thinking, but if it is in fact these new designer drugs, then it is not the quality, but the chemical formation of it. So I think they are in Baltimore. And the problem is that we are not sure what they are. There are no labs that can test for that in the area.

When I was asked to be on this panel, I called a few people in Baltimore and asked about it, if they had done samples, and I was informed at that point that there were only two places to get the test done, and that it was expensive. So I think the testing needs to be done, and more test centers need to be set up.

Dr. NURCO. Didn't you know someone who died a little while ago of an overdose?

WILLIAM. Yes. There have been quite a few overdoses, actually, in the Fells Point area of Baltimore—two that I can think of.

Senator HAWKINS. Synthetic or designer drug deaths?

WILLIAM. We are not sure.

Senator HAWKINS. You do not know which one?

WILLIAM. We don't know.

Dr. NURCO. That is the problem, as he points out. The "labs" are not equipped to do the proper testing at this point in time, and until inexpensive laboratory techniques are developed, we will not have good information to deal with this problem.

Senator HAWKINS. Is it less expensive, William, to purchase synthetic heroin?

WILLIAM. No, it is not. It is the same price.

Senator HAWKINS. Does the dealer tell you it is synthetic and more powerful, or does he say it is the same stuff?

WILLIAM. No. What they are doing is misrepresenting it as "China white" heroin or "Mexican brown," and as Dr. Nurco said, they are using all kinds of cutting agents—you can make "Mexican brown" by putting instant coffee in it, and cutting it up, and it will turn brown.

Senator HAWKINS. Did you hear the previous panel say that it comes in an array of colors in California?

WILLIAM. Oh, yes.

Senator HAWKINS. Has that happened in Baltimore yet?

WILLIAM. I have only seen brown and white.

Senator HAWKINS. Have you ever sought treatment for heroin addiction?

WILLIAM. Yes.

Senator HAWKINS. Did it work?

WILLIAM. No.

Senator HAWKINS. Was there any treatment you received that you felt may have been more effective than another program that you were enrolled in?

WILLIAM. I would say that the personal interaction treatment, one-on-one therapy, this type of treatment. There was a thing done back in 1976 with yoga in conjunction of biofeedback, and it was very effective. I do not find methadone very effective at all.

Senator HAWKINS. How long did you stay in the program?

WILLIAM. I was on methadone for 12 years.

Senator HAWKINS. How old are you now?

WILLIAM. Thirty-eight.

Senator HAWKINS. Have you ever used PCP?

WILLIAM. Yes, I have.

Senator HAWKINS. And what was the effect produced when you used PCP?

WILLIAM. Hallucinations, paranoia, kind of a classic schizophrenic reaction.

Senator HAWKINS. Are you aware that when PCP was used in Yellowstone to tranquilize the bears, that it actually caused the opposite effect and caused them to be very violent?

WILLIAM. Yes, yes, I am.

Senator HAWKINS. Did you stop using PCP?

WILLIAM. Yes, I did.

Senator HAWKINS. Have you used cocaine?

WILLIAM. Yes, I have.

Senator HAWKINS. Do you use it now?

WILLIAM. No.

Senator HAWKINS. Heroin?

WILLIAM. Heroin is my penchant, yes.

Senator HAWKINS. Are you nervous that the next batch you might buy might be some of this stuff that would cause you to have Parkinson's disease?

WILLIAM. Very much so. I am not only nervous that the next batch, but that the last batch could have.

Senator HAWKINS. I see.

Vincent, do you have a statement, or would you just like us to ask you questions? Tell us your story, Vincent.

VINCENT. Well, my story is pretty much the same as William's. Everything that he has said here is pretty much the same words that I could say.

Senator HAWKINS. How old are you?

VINCENT. Thirty years old.

Senator HAWKINS. And how long have you been using drugs?

VINCENT. For 14 years.

Senator HAWKINS. Heroin, mostly, or have you tried them all?

VINCENT. The majority is opiates, heroin, Dilaudid, methadone. At the present time, I am on the methadone program.

Senator HAWKINS. You are in the methadone treatment program?

VINCENT. Yes, ma'am.

Senator HAWKINS. How long have you been there?

VINCENT. About 16 months.

Senator HAWKINS. Well, we congratulate you and hope that you stay there.

VINCENT. Thank you.

Senator HAWKINS. Do you have any advice for this panel on this particular problem of these synthetic drugs?

VINCENT. As far as the synthetic drugs, the film that I saw was very impressive. For the last 10 months, I have not used heroin. I have used cocaine, not a whole lot, but every now and then. But I really feel that at the present time, I do not want to go back to using heroin, not for the simple fact of what I have seen here today on the film—it really scares me, and pardon the expression, but it scares the hell out of me.

Senator HAWKINS. So if we were to show this film—this was a 6-minute edit of I think a 30-minute film that we have all seen. If we were to show either an abridgment of the film we have just seen, or the whole 30 minutes of it, to, say, sixth graders, do you think it would be effective? Would it have affected you if you saw it when you were in the sixth grade?

VINCENT. Not in the sixth grade, but I think to a lot of junior high school students.

Senator HAWKINS. Starting in seventh, eighth, ninth grades, then?

VINCENT. I started using drugs when I was in junior high school. I think that a lot of junior high school kids, if they were to see this film, they might change their minds a lot about wanting to try heroin, or any kind of drug that they had to use intravenously, because it would scare them; I guarantee it would scare them.

Also, I am concerned about a lot of kids my age. When I started drugs, back when I was growing up, drugs were the "in" thing, and now there are a lot of kids that are using drugs that are younger. Like William has said and I am saying now, when I was using heroin, I was served by young kids anywhere from 9, 11, 12 years old that were using and selling heroin, cocaine, pills.

I have a son who is 8 years old, and I have not really sat down with him and talked with him about it, because I do not feel he is really at the right age to really talk to him about it, but very soon in the near future, I will sit down and talk with him about it, because he knows that his dad has been through a lot of trouble, has had a lot of trouble with drugs, and has been to jail for drugs.

I feel that in the future, I would like to get a chance to speak with a lot of kids, teenagers, high school students, about drugs, to give them the knowledge that I have and to give also you folks here the knowledge that I have about drugs and using drugs.

Senator HAWKINS. We really appreciate that. You can help more than anyone, I believe, because you have to have been there, as Dr. Nurco tells us.

How did you earn the money to buy the drugs you used?

VINCENT. I have always considered to maintain a job. If I was not working, I was stealing, sometimes robbing for the money. A lot of times—drug-related crimes. In order to get the money for drugs was what caused me to go to jail, because it was more or less drug-related. If I did not have the money, I would go out and maybe steal or rob to get the money for the drugs. It is something that I have been away from for a while, as far as the heroin scene—close to a year.

Senator HAWKINS. Were there drugs available in jail?

VINCENT. They were available in jail. I mean, they weren't really plentiful, but the times that I was in jail, I stayed away from

drugs. I was more into my health. As far as my health, I mean exercising, et cetera.

Senator HAWKINS. We have been joined by Senator Dodd, who is the ranking member on this committee and very interested in all of our hearings. He is a very active participant on many committees. I am sure he would have been here earlier had he not had other assignments, also. So, we welcome you at this time, Senator Dodd. We have had the medical panel and an exceptional film shown by Mr. Robert Roberton from California. This is a panel of individuals who have used synthetic drugs, with Dr. David Nurco, who has been a long-time friend. He was also responsible for the most scientific study of crime connected to drug use in this country, and it has been the model that we use to try to find out how much drug abuse costs us in this country.

If you have a statement, we will be happy to have it at this time.

Senator DODD. Thank you, Madam Chairman. I appreciate your kind comments, and you are right, I am running around with hearings all over the place this morning. I am sorry I missed the medical panel. I am glad I had an opportunity to listen briefly to two of the witnesses we have here. I am looking forward to Mr. Lawn's testimony.

I have an opening statement which I would ask unanimous consent to be made a part of the record.

Senator HAWKINS. Surely.

Senator DODD. I am particularly anxious to hear from Mr. Lawn. We had a hearing, if you will recall, a few weeks back, where I had asked, in fact, the administration what they were doing about designer drugs and would they report to the committee what activities were under way. I presume this morning I will get a chance to hear, because we have not yet had an answer to that inquiry.

Senator HAWKINS. No. That was why we called this hearing. I recall that you and I discussed that and said we would have a hearing on this topic.

Senator DODD. And I know now there are a couple of bills kicking around. I think Senator Cranston and Senator Thurmond each have bills in, at least making some suggestions on what we might do in that regard.

I cannot resist—it is always somewhat dangerous to do something just for a few days on these matters, but in Connecticut, I went out with our undercover operations in the State one evening on their narcotics runs and pickups, and I was somewhat disguised—disguised well enough, anyway—I do not know whether I was pleased or happy about it; sometimes we politicians like to think we get recognized everywhere, but I was just as glad I was not—in a relatively modest, not a big city in Connecticut at all. And I was able to buy half a gram of cocaine quicker than I was ever served a hamburger at McDonalds, just curb service. This was not a requirement of going in anywhere; it was just pulling up to the corner, a couple of blasts of the horn—on, I might add, a pouring, raining night; it was not a night when there was a lot of activity on the streets. But within about a minute and a half, I had my half gram of cocaine.

And the problem—and I would just like the two of you to comment on this, because this was one of the things that the State of

Connecticut people, the DEA people that are active in the State, point out—a lot of the arrests are made of that fellow who came out from that particular building to make the transaction, the $50 deal. The State can afford to come up with *x* amount of money to make those buys, those small amounts of buys, and those are the people they put on film, those are the people they nail.

The DEA people just think they are too small, and they are far more interested in the first person, the original supplier—say, in our case in Connecticut, out of New York—and there is a person there in the middle who completely slips through the net. He is the person buying from the supplier in New York. There may be more people involved—for the sake of discussion, let me make it three—the guy in New York, the guy who is sitting inside that building in Connecticut, and the person who runs out of the building to sell to me. The DEA goes after the guy in New York. The State of Connecticut goes after the guy who runs out on the street. And the guy in the middle goes virtually scotfree, because there is not the money in the State to make the buys from the guy in the middle, and the DEA does not want to waste their time on "smaller fish". And I think their arguments have a lot of justification. They prefer to go after the larger suppliers.

Was that an accurate—in your experience as people on the street, is that the case?

WILLIAM. Yes; the person who does the middleman part of the deal does not get caught because he doesn't come out, he is not as open about it.

Senator DODD. So they are really almost the untouchables.

WILLIAM. Yes; basically.

Senator DODD. They were accurate in that.

The other thing which one of you said, and it may have been you, William—education, much more so in many ways than legislation. And we have legislated up here for years on this subject matter. It goes back to the days of my father, when he was the chairman of the Subcommittee on Juvenile Delinquency in the 1950's, and held hearings on drug abuse—the Safe Streets Act, the omnibus crime bill—my God, there has been one major piece of legislation after another over the years, and we still find the problem growing. And yet, I find that the educational efforts really are the ones that make a difference, to the extent we are able to really develop them.

I just wonder if you might have some ideas. Vincent mentioned the idea of talking to his child and talking to high school students and so forth.

Quite candidly, with all due respect—and I am 10 years older than you are, Vincent—we are getting a little too old to talk to high school students. We suffer from the same problem of age. They are more inclined, I have found, to be impressed by their peers than they are people whom they perceive as being too old to really understand what they are going through, as they would describe it.

I wonder if you might comment on that, both of you.

VINCENT. As far as talking about it to people, I don't think that being too old to talk to anyone who has a drug problem—I feel that statement about being old is wrong. I mean, as far as talking to

people who have drug problems or people that are starting to get into drugs, if you talk to them about it—then, those people themselves are the only ones that can stop doing drugs. You can talk and talk and talk and keep on talking. But basically, you can help them along. It is nice to have someone to talk to about drug addiction. I go to counseling sessions once a week and talk with a counselor about it in the program that I am on. We have very good sessions when we speak. And she is there to help me, but she knows and I know that I am the only one that can stop doing drugs when I want to stop.

Senator DODD. What about the promotion of it? There is a program in Connecticut called VTOM, which has been an excellent program of rehabilitation. I spend about half a day there, and the oldest person I talked to there was 15 years old—and they were a lot older than I, in terms of life experience and what they have been through.

I asked them as sort of a passing question—because I have always been suspicious of people who relate music and television or movies and the promotion of this kind of activity, and yet without exception, every one of these children—and they really are children at that age—said that that had had, that is, the MTV kind of stuff, a lot of those rock video things, that they had really had far more of an impact on their decision to become involved in this than they were willing to admit when they were in it, or that some of us who are concerned about first amendment rights and so forth may be willing to come to terms with.

One kid said, "Look, I was 11 years old when I started this stuff"—he was extremely articulate, I might add. He said, "I was not able to draw the nice, logical conclusions. I knew that my greatest hero was a guy who was a rock star, and I wanted to be like him." I knew from all the literature, the magazines—whether he was quoted accurately or not is another matter, but the fact is that there was a tremendous amount of drug-related activities associated with this particular rock star.

"So my conclusion was, logically, if I wanted to be like him that I should adopt his lifestyle." He said, "I realize today, that is insane, and I made a terrible mistake." He was not even sure that all of the information about that person is correct.

But I wonder if you might comment on that yourself, either one of you—William, I am not addressing this just to Vincent. If at any point you want to step in, please do.

WILLIAM. I think obviously censorship is not the answer. The Moral Majority has not come up with a good program yet.

Senator DODD. That is the problem I have as well, but do you think there is a responsibility here on the part of people within that industry where there is and has been a tremendous amount of association, almost humorous, light hearted, the professionals and medical people and so forth really do not know what they are talking about. I mean, you know that attitude. You and I have been there. We have seen it all.

WILLIAM. Well, certainly, there is a responsibility in the industry, but it is the same responsibility that carries through to sports.

Senator HAWKINS. Sure, sure.

Senator DODD. Yes; I agree. But are they meeting that responsibility? I mean, it is one thing for an athlete that you and I might think of as a big hero, and we find out next week has been on drugs for 5 years or whatever else. That is an individual kind of situation. Whereas the intentional promotion of the use of drugs as being somehow related to a sense of happiness and glee and so forth—there is a distinction there, I think. I do not know if I am articulating it as well as I would like, but I think there is an intentional promotional activity which goes on in one side, and the abuse by individual people who are held up as models in society, in sports, for instance.

WILLIAM. Well, I really do not think that music leads to drug abuse per se. A lot of musicians do use drugs. Music and drugs are synonymous. Other than changing all the musical groups and turning them around into a nondrug vein—maybe get two or three groups to come out with a nondrug program. I think there is one called "Twisted Sister"—I am not sure of the name—but they are pushing a nondrug kind of thing. I think that would be important.

Senator DODD. Yes. That is more what I am referring to. I am not suggesting that music—I hope I did not give that impression. That is the problem I have. I have the very problem you mentioned. I have a problem with the whole first amendment stuff and censorship. I do not believe that is the answer at all. I do believe it is education and an assumption of responsibility in a sense by people in the business, where they obviously are appealing to a particular age group, they are really pitching them, and that is my concern.

WILLIAM. As Vincent said—I have a thought on the other topic that you asked about, which was education——

Senator DODD. Sure.

WILLIAM. You alluded to that they are not going to listen to older people. Why not put some ex-drug abusers out there to talk to them; enlist some of the already street educated people to go out there and tell them. The prison system has a "Scared Straight" program which is evidently effective.

Senator DODD. A film, yes; I have seen it.

WILLIAM. I think that that would really be a positive thing to do. I have done this in a couple of schools in Baltimore, and whether it did any good or not, I am not sure, because I did not follow it up. But I think a program of that type would be very beneficial.

Senator DODD. Marsha Renwanz who is here from my staff asked me to follow up. I apparently missed this, William, in your discussion earlier. I talked about the middlemen myself, the sort of untouchables. I gather that the age of these people, even the ones who are runners, they are recruiting kids who would fall under the juvenile statutes and not adult statutes, and thereby become sort of insulated from the criminal justice system because they are children.

Is that accurate?

WILLIAM. Very much so. The last heroin that I bought on the street, I bought from a 12-year-old on a Huffy bike.

Senator DODD. And that was not the exception, I gather?

WILLIAM. Oh, no. That is not at all unique. In fact, that is the norm.

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Senator DODD. Well, I thank both of you for coming. I really appreciate your being here. You are already contributing to that educational process, and maybe there is one person who will listen to what you are saying here today and will change a lifestyle.

Thank you.

Senator HAWKINS. And I thank all of you for coming. Thank you, Dr. Nurco, and thank you, Senator Dodd.

Senator HAWKINS. Our last panel consists of one of our Nation's top law enforcement officers, Mr. Jack Lawn. He has just recently been confirmed as Administrator of the Drug Enforcement Administration, and we want to congratulate him for this well-deserved appointment.

I have worked with Mr. Lawn for a number of years now and I am well aware of his dedication and commitment to the eradication of drugs in this Nation.

We will ask for your statement at this time.

STATEMENT OF HON. JACK LAWN, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, WASHINGTON, DC, ACCOMPANIED BY FRANK SAPIENZA, DEA CHEMIST, AND RONALD BUZZEO, ACTING CHIEF, DIVERSON CONTROL UNIT

Mr. LAWN. Thank you, Madam Chairman.

If I could, I will begin by introducing Mr. Frank Sapienza, a DEA chemist, and Mr. Ronald Buzzeo who is the Acting Chief of our Diversion Control Unit.

I do have a formal statement and brief reading statement, if I may begin.

Senator HAWKINS. Surely.

Mr. LAWN. Madam Chairman, Senator Dodd, I appreciate the opportunity to appear before you to discuss the very serious problem of designer drugs which we have heard so much about this morning.

The term "designer drugs" refers to clandestinely produced substances which are chemically and pharmacologically similar to substances listed in the Controlled Substances Act. The aim of the clandestine chemist is to manufacture substances which produce the effects of controlled drugs but are not controlled under the Controlled Substances Act because they are slightly different chemicals.

Designer drugs can be manufactured relatively inexpensively, as we have heard this morning, and they have a very high markup on the street.

The designer drug phenomenon is an attempt by unscrupulous individuals to reap tremendous profits from the distribution of dangerous drugs of abuse without fear of prosecution.

The concept of producing analogs with controlled substances in an effort to circumvent the existing drug laws is not new. The clandestine production, distribution, and use of a number of mescaline analogs such as MDA, MMDA, STP, TMA, first appeared in the late 1960's. The enactment of the Controlled Substances Act of 1970, which provided for administrative scheduling, was a response to this phenomenon. Later, in the 1970's, chemical variance of methaqualone, PCP, and amphetamines surfaced.

The significance of the current wave of designer drugs is the production of very potent analogs of synthetic narcotics which can be substituted for heroin in the illicit market.

These substances pose tremendous public health and safety hazards. They also create numerous enforcement problems. The designer drugs of the eighties are focused on chemical variation of two major synthetic narcotic analgesics—fentanyl and meperidine—and on the hallucinogenic amphetamines. Each of these groups of designer drugs, the analogs of fentanyl, meperidine, and amphetamine, carry with them a unique set of dangers to the user.

Fentanyl analogs, which produce heroinlike effects, can be hundreds of times more potent than heroin and pose a very significant risk of overdose and death, as we have heard this morning. Last year, we had reports of 31 overdose deaths associated with fentanyllike substances. In the first 5 months of this year, we already have reports of 26 overdose deaths.

While the use of fentanyl analogs carries a substantial risk of drug overdose, the use of MPPP, a meperidine analog, carries an additional health risk. The synthetics of MPPP, unless performed under carefully controlled conditions, result in the formation of a byproduct known as MPTP, which induces irreversible symptoms of Parkinson's disease, which we have seen on the videotape. This disease is characterized by tremors, muscular rigidity, slowness of movement and speech, and a masklike, expressionless face. In addition to the link to Parkinson's disease, the meperidine analogs are also up to 70 times more potent than the parent drug and lethal at much lower doses.

We have several charts which, I think better than words, will allow us to see the problems as we have described them.

In the narcotic designer drug, fentanyl, giving morphine a numerical value of 1, fentanyl would be 300 times more powerful than morphine; the next, 900 times more powerful than morphine, and the 3-methyl-fentanyl, up to 1,100 times more poweriul than morphine.

As we look at this chart depicting the overdose deaths of the analogs of fentanyl, we can see, for example, in 1980, there were 13 associated deaths. With the control of fentanyl, the chart shows a tremendous decline. Again, with the analogs beginning in late 1984, we recorded 31 deaths; as of the end of May of this year, 26 deaths with the projection that by the end of this calendar year, we will have reported 62 deaths because of these analogs.

Senator DODD. Excuse me. I am confused about why in 1981, and then bang, it jumps up again. You said it, but I did not understand you. It drops down to 1 in 1981, and then——

Mr. LAWN. Yes, sir. In 1981, we were able to control alphamethyl-fentanyl, which was causing the deaths in 1980, so the control procedure, which we now have on an emergency basis as a result of the Comprehensive Crime Control Act, shows that it can be effective as experienced in 1981, 1982.

Senator DODD. I see.

Senator HAWKINS. But these are the permanent, rather than the emergency?

Mr. LAWN. That was the permanent, yes, ma'am. That was prior to the passage of the Comprehensive Crime Control Act in 1984.

Again, we can see the exhibits anaylzed in the DEA laboratory system, and the tremendous increase in the fentanyl analogs being isolated in our laboratories. There were 9 in 1983, 42 in 1984, and again, 24 as of the end of May 1985, with a projection that 58 exhibits will have been examined by our laboratory by the end of this year.

MDMA, which produces effects similar to the hallucinogen, MDA, and methamphetamine, has been associated with several medical emergencies, and users are seeking help at drug abuse treatment centers. Individuals taking multiple doses of MDMA are reporting severe anxiety reactions, paranoia, fear, sleep problems, and depression. Moreover, recent studies conducted at the University of Chicago show that at low doses, MDA destroys nerve terminals in the brains of rats. Preliminary work with MDMA indicates that this drug produces similar neurotoxicity. These neurotoxic effects are likely in humans.

The profit motive is a major factor in the manufacture and distribution of designer drugs. It is estimated that one kilogram of the fentanyl analog, which produces approximately 50 million dosage units, could be manufactured for under $2,000 and have a retail street value of over $1 billion. Obviously, the financial rewards of such an endeavor are enormous and enticing.

DEA has used every resource available to it to combat the designer drug problem. When "China White" appeared in California in late 1979 and caused over 20 overdose deaths, DEA administratively controlled the drug in schedule I of the Controlled Substances Act. This action apparently minimized the production. This process, however, took 9 months. Realizing the need for quicker administrative scheduling under CSA for this dangerous group of drugs, the administration submitted as part of the Comprehensive Crime Control Act of 1984, a provision for an emergency scheduling procedure. Since October 1, 1984, DEA has had the authority to temporarily place the substance into schedule I of the Controlled Substances Act if the substance poses an iminent hazard to the public safety. In the last 4 months, DEA has used this authority to expeditiously place the most dangerous and highly abused designer drugs which we have identified to date into schedule I of the CSA.

The fentanyl analog, 3-methyl-fentanyl, which was responsible for the majority of designer drug deaths in California, was controlled in April 1985. MDMA was placed under control as of July 1, and the control of two meperidine analogs, MPPP and PEPAP, will become effective on August 12.

Despite the effective use of the emergency scheduling authority and DEA's subsequent enforcement actions, individuals continue to evade the law by producing and distributing new analogs faster than they can be controlled.

Indeed, the fentanyl analogs seized from two suspected clandestine chemists in early June 1985 were uncontrolled. Although emergency scheduling considerably shortens the time needed for the scheduling process, there still exists a time lag between the production of these new designer drugs and their subsequent control under CSA.

The provisions of Senate bill 1437 would effectively close this gap in our current authority by making it illegal to manufacture with

the intent to distribute, or to possess with the intent to distribute, or to distribute, a designer drug intended for human consumption unless such action is in conformance with the Federal Food, Drug and Cosmetic Act. Violations of this provision would carry a maximum penalty of 15 years and a potential fine of up to $250,000.

Careful defining of the term "designer drug" and provision for the legitimate activity under the Federal Food, Drug and Cosmetics Act assures that the proposed legislation would impact only on the undesirable activity and not on the legitimate manufacture and research. The approach taken by this bill provides for an effective and, most importantly, an immediate law enforcement response to the manufacture and distribution of designer drugs.

No longer would individuals be able to circumvent the Controlled Substances Act through successful manipulation of the chemical structure of potent and dangerous drugs.

The designer drug problem is indicative of the increasing complexity and technical nature of the drug abuse and trafficking situation. DEA has responded to this problem using every tool available to it and has to this point managed to put forward an effective effort against the most serious of these designer drugs.

However, the nature of this drug phenomenon is such that the traffickers can and are circumventing our efforts by creating new, uncontrolled analogs of controlled drugs. Without additional legislation, we will continually be one step behind many of these drug traffickers. This is a situation which obviously is not to be tolerated, when people are being killed and crippled by these unscrupulous individuals who manufacture and distribute designer drugs.

Thank you very much, Madam Chairman.

[The prepared statement of Mr. Lawn follows:].

STATEMENT OF JOHN C. LAWN, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Chairman Hawkins and Members of the Committee:

I appreciate this opportunity to appear before you to discuss the very serious problem of designer drugs and to specifically comment on the provisions of S. 1437.

The designer drug phenomenon is fast becoming a serious challenge to the United States efforts against drug trafficking and control. This new dimension to the clandestine laboratory problem is being spearheaded by sophisticated chemists who manipulate the molecular structure of powerful, controlled drugs to create new drugs not controlled under Federal or state statutes. The proliferation of these designer drugs requires that we review our existing authorities to control this new threat to the public safety.

BACKGROUND

By way of background, the term designer drugs refers to clandestinely produced substances which are chemically and pharmacologically similar to substances listed in the Controlled Substances Act (CSA) but which are not themselves controlled. These analogs or chemical variants of controlled substances are not subject to the provisions of the Controlled Substances Act unless or until they are controlled in one of the five schedules

of the CSA. The aim of the clandestine chemists is to manufacture substances which produce the effects of controlled narcotics, stimulants, depressants or hallucinogens, but because they are slightly different chemicals they are not controlled under the CSA. The designer drug phenomenon represents an attempt by unscrupulous individuals to reap tremendous profits from the distribution of dangerous drugs at the expense of the public health and safety and without fear of prosecution.

The concept of producing analogs of controlled substances in an effort to circumvent the existing drug laws is not new. The clandestine production, distribution and use of a number of hallucinogenic amphetamine analogs of mescaline such as MDA, MMDA, STP and TMA first appeared in the late 1960's. The enactment of the Controlled Substances Act in 1970 which provided for administrative scheduling of substances was, in part, a response to this phenomenon. Chemical variants of methaqualone, PCP and amphetamine surfaced later in the 1970's. All of these early designer drugs were subsequently placed under the Controlled Substances Act through the administrative scheduling mechanism. The novel aspect of the current wave of designer drugs is the production of very potent analogs of synthetic narcotics which have been substituted for heroin.

The designer drugs of current concern focus on chemical variations of the Schedule II synthetic narcotic analgesics, fentanyl (marketed as Sublimaze®) and meperidine (marketed as Demerol®). Fentanyl is a short-acting, highly potent narcotic which is used as a surgical anesthetic. In humans it is about 100 times more potent than morphine. Meperidine is a narcotic analgesic approximately 1/6 to 1/8 as potent as morphine in humans. There are numerous chemical variants of both of these drugs which produce effects similar to those of morphine and heroin. Additionally, analogs of the hallucinogenic amphetamines continue to surface, as evidenced by the recent surge in the use of MDMA, known on the street as "Ecstasy."

As the lead Federal agency responsible for curtailing drug trafficking, DEA has been closely monitoring the designer drug phenomenon since its inception. I will now describe the current status of the problem involving fentanyl, meperidine and hallucinogenic amphetamine analogs, DEA's efforts to combat the designer drug problem, my assessment of the impact of these efforts, and the need for further legislation.

THE DESIGNER DRUGS OF THE '80's

The alpha-methyl analog of fentanyl was the first of the narcotic designer drugs encountered in the illicit drug traffic. Although it was not specifically identified by the DEA Special

Testing and Research Laboratory until January 1981, alpha-methylfentanyl was associated with narcotic overdose deaths in California as early as December 1979. Alpha-methylfentanyl was sold on the street to heroin addicts as synthetic heroin or "China White." It was associated with over 20 overdose deaths in California between December 1979 and December 1981. One overdose death each in Oregon and Arizona was also attributed to alpha-methylfentanyl during this period. Effective September 22, 1981, DEA placed alpha-methylfentanyl into Schedule I of the CSA by its administrative process. This action apparently eliminated the production and distribution of alpha-methylfentanyl. Other fentanyl analogs, however, were produced almost immediately to take the place of alpha-methylfentanyl in the drug traffic.

Since 1981, DEA laboratories have identified seven other fentanyl analogs. Over 75 drug evidence samples submitted to DEA laboratories have contained fentanyl analogs. More than 65 of these samples have been analyzed since January 1984--24 since January 1985. Most of these analogs had been described in the scientific literature. Two of the analogs, however, could not be found in the scientific literature. Some, such as para-fluorofentanyl, were encountered only one time, while others, such as 3-methylfentanyl, have been identified in over 40 submissions to DEA laboratories.

The health risks attendant to the use of the various fentanyl analogs are greater than those associated with the use of traditional narcotics, such as heroin or morphine. The high potency of the fentanyl analogs creates a substantial risk of fatal overdose. Indeed, the various fentanyl analogs have been associated with more than 95 known overdose deaths since December 1979. There were at least 31 overdose deaths in 1984 and at least 26 thus far this year. A continuing increase in the availability and use of these substances since January 1984 is borne out by the increase in submissions of fentanyl analog samples to forensic laboratories and the greater number of fentanyl analog related deaths. With very few exceptions, these reports have come from California. Moreover, in those cases not reported in California, the source of the fentanyl analog was identified as California.

Researchers at the University of California at Davis recently attempted to determine the incidence of fentanyl analog use by clients of several California methadone maintenance programs through the use of urine screening tests. Their results showed that approximately 10% (range 0-24%) of the clients tested had used fentanyl analogs either knowingly or unknowingly. The fentanyl analogs are extremely potent; only minute quantities are necessary to produce the desired effects. Further, the clandestine production of these substances yields a number of by-products and impurities. Detection and identification of

fentanyl analogs as a class, or individually, in biological or powder samples requires considerable time, expertise and sophisticated equipment not available to all analytical laboratories. In light of the above, it is highly likely that the prevalence of fentanyl analogs is underreported and, therefore, a clear picture of the magnitude and scope of the fentanyl analog problem is difficult to measure.

All of the fentanyl analogs identified in the illicit traffic are potent narcotics with rapid onsets and relatively short durations of actions. They produce a spectrum of heroin-like effects including euphoria, addiction-sustaining liability and respiratory depression. In humans, these fentanyl analogs range in potency from about 10 to 250 times that of heroin. Consequently, whereas a 1.0 gram quantity of heroin would yield approximately 200 dosage units, the same quantity of 3-methylfentanyl would yield 50,000 dosage units. The scientific literature describes analogs of fentanyl even more potent than 3-methylfentanyl. Fortunately, there are no reports of these substances in the illicit drug traffic.

It is evident from the type of compounds produced and the methods of synthesis employed that the individuals who are operating these clandestine laboratories have a substantial amount of education and training in chemistry. However, the impurities and by-products present in the samples analyzed

indicate that these chemists do not practice quality control. We surmise that maximum profits appear to be more important than quality products. It is estimated that one kilogram of a fentanyl analog, which is equivalent to as many as 50 million dosage units, could be manufactured for under $2,000. The street value of this quantity of fentany analogs would be over one billion dollars. Obviously, the financial rewards of such an endeavor are enormous and enticing.

While the use of the fentanyl analogs carries a substantial risk of drug overdose, the use of MPPP, a meperidine analog, carries an additional health risk. The synthesis of MPPP, unless performed under carefully controlled conditions, results in the formation of a by-product known as MPTP, a neurotoxic substance which induces an irreversible syndrome in man resembling Parkinson's Disease.

The first reported episode of MPPP abuse came to light in 1976 when an individual who synthesized MPPP for his own use sought treatment for Parkinson-like symptoms after using MPPP. Parkinson's Disease is characterized by tremors, muscular rigidity, slowness of movement and speech, and a masklike, expressionless face. In 1982, DEA laboratories analyzed a number of MPPP samples taken from individuals who were hospitalized with this syndrome in California. These samples also contained MPTP. By the summer of 1983, neurologists at the Santa Clara Valley

Medical Center reported that they were treating seven individuals for a Parkinsonian syndrome after their intravenous use of MPPP and MPTP. The Center for Disease Control, in a study conducted in California in January 1985, indicated that many more individuals may have been exposed to MPPP/MPTP since 1982. Although some of these individuals do not now exhibit these symptoms, it is possible that they may develop Parkinsonian syndrome as they age.

In 1985, DEA laboratories identified yet another meperidine analog, PEPAP, in the illicit drug traffic in California. It is also believed that chemists in a large-scale clandestine PCP laboratory seized by DEA in Brownsville, Texas in late 1984 were attempting to synthesize PEPAP. Only the PEPAP intermediate in the reaction sequence was found at this laboratory. Synthesis of PEPAP also results in the formation of a by-product similar in structure to MPTP which is known as PEPTP.

Both of the meperidine analogs identified by DEA laboratories (MPPP, PEPAP) produce morphine-like effects and differ mainly in their potency. MPPP is up to 30 times more potent than meperidine, while PEPAP is up to 70 times more potent than meperidine. MPPP is also lethal at significantly lower doses than meperidine.

Currently, the narcotic designer drug problem appears to be confined primarily to portions of California. Furthermore, drug abuse indicators suggest that it is a relatively small but significant and increasing problem there. Recent seizures of kilogram quantities of fentanyl analogs indicate an alarming increase in the potential availability of these substances. The potential spread of the synthetic narcotic analogs to other sections of the country is a real and frightening possibility and causes us concern. This possibility has become a reality in the case of one designer drug, MDMA, which has spread to many sections of the country.

MDMA, also known as Ecstasy, XTC or ADAM, is an analog of the Schedule I hallucinogen MDA and the Schedule II stimulant methamphetamine. Pharmacologically, MDMA produces effects similar to those of both MDA and methamphetamine. This designer drug is reminiscent of the so-called "alphabet soup psychedelics" of the 1960's. In addition to being distributed in the usual underground drug channels, MDMA was used by a small group of psychiatrists as an adjunct to psychotherapy, even though the FDA has not approved this use.

MDMA was first seen in the illicit drug traffic in 1972 and infrequently in the illicit drug traffic during the 1970's. The last few years has seen a spread and increase in the clandestine production, distribution and use of MDMA in many sections of the

country. Open promotion of MDMA as a legal euphoriant surfaced in some areas. Pamphlets entitled "Ecstasy, Everything Looks Wonderful When You're Young and on Drugs," "Flight Instructions for a Friend Using XTC" and "How to Prepare for an Ecstasy Experience" appeared on college campuses. Street prices have ranged from $8 to $20 per dosage unit or $70 to $100 per gram. Over 70,000 dosage units of MDMA have been submitted to DEA laboratories since 1978. It has been reported that one individual in Dallas, Texas was distributing 30,000 dosage units of MDMA per month. Unlike the fentanyl and meperidine analogs which have been geographically limited, MDMA abuse has become a nationwide problem.

The use of MDMA has been associated with several medical emergencies and users have been seeking help at drug abuse treatment centers. Individuals have been taking multiple doses of MDMA and have reported severe anxiety reactions, paranoia, fear, sleep problems and depression. Moreover, recent studies conducted at the University of Chicago show that low doses of MDA destroy serotonergic nerves in the rat brain. Preliminary work with MDMA indicates that MDMA produces similar neurotoxicity. Serotonin plays a major role in pain perception, sleep, mood, aggression and sexual behavior. Experts believe that humans taking MDA or MDMA in reported dosages of 100-120 mg. could experience neurotoxic effects.

DEA RESPONSE

The Drug Enforcement Administration sees designer drugs as a serious threat to public safety. However, until and unless these substances are listed under the CSA, DEA can take no enforcement action against the individuals responsible for the production and distribution of these analogs. DEA has used its scheduling authority to place several of the most dangerous and available designer drugs into Schedule I. In the case of alpha-methylfentanyl, DEA used the traditional scheduling provision of the CSA to place it into Schedule I effective September 22, 1981. Even if expedited, these types of scheduling actions under the normal administrative process of the CSA usually take several months.

Realizing the need for quicker administrative scheduling under the CSA for this dangerous group of drugs, the Administration submitted, as part of "The Comprehensive Crime Control Act of 1984," a provision for an emergency scheduling procedure. This new authority provides DEA with the most important tool currently available to combat the designer drug problem. Title V of this Act, the "Drug Enforcement Admendments," gave DEA the authority to temporarily place a substance into Schedule I of the CSA if the substance poses an imminent hazard to the public safety. The legislative history

shows that Congress envisioned that the emergency scheduling provision would be used for designer drugs.

In the last four months, DEA has used this authority to expeditiously place into Schedule I of the CSA the most dangerous and highly abused designer drugs identified to date. DEA's first emergency scheduling action placed 3-methylfentanyl into Schedule I effective April 15, 1985. 3-methyfentanyl is the most potent of the fentanyl analogs identified thus far in the illicit traffic and was responsible for most of the designer drug overdose deaths in the San Francisco Bay Area in 1984 and 1985. Effective July 1, 1985, DEA placed MDMA into Schedule I of the CSA using the emergency scheduling provision. Escalating nationwide abuse of MDMA and research which indicated that the use of MDMA may result in neurotoxic effects led to the scheduling of "Ecstasy." I am pleased to report that in the week immediately following the scheduling of MDMA, DEA made several arrests of distributors of "Ecstasy" in Texas. Also, a laboratory equipped to synthesize and tablet MDMA was intercepted en route to Mexico from California.

Most recently, DEA has moved against MPPP, which has been linked to the development of Parkinson's Disease in its abusers, and a similar substance known as PEPAP. These substances will be in Schedule I effective August 12, 1985.

THE NEED FOR ADDITIONAL LEGISLATION

Despite the effective use of the emergency scheduling authority and DEA's subsequent enforcement actions, there remain individuals who continue to evade the law by producing and distributing new analogs faster than they can be controlled. Indeed, the fentanyl analogs seized from two suspected clandestine chemists in early June 1985 were uncontrolled analogs of fentanyl. It is only after these new analogs are identified and placed under emergency control that there can be any criminal liability. Although the emergency scheduling process has considerably shortened the time needed for scheduling actions, there still exists a time-lag between the production of these new designer drugs and their subsequent control under the CSA. Clearly, this loophole must be closed if we are to effectively combat the clandestine designer drug chemists and guard against hazards to the public safety. A key to effective action against designer drugs cannot be based on the individual substances themselves, since they can be readily modified and the number of these drugs may be infinite. Rather, we must turn our attention to the act of manufacturing and distributing these designer drugs.

The bill S. 1437 takes this type of approach. Specifically, the proposal would add a new section, 403A, to the Controlled Substances Act (21 U.S.C. §843A) to make it unlawful to

manufacture with the intent to distribute, to possess with the intent to distribute, or to distribute a dangerous class of substances known as designer drugs intended for human consumption, unless such action is in conformance with Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355, regarding new drug approval. The term designer drug is defined for purposes of the proposed provision to mean a substance other than a controlled substance that has a chemical structure substantially similar to that of a controlled substance in Schedule I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedule I or II.

This proposal would impact on the designer drug phenomenon by making it illegal for clandestine chemists to manufacture and distribute these substances. Great care has been taken to assure that the proposed legislation would impact only on the undesirable activity and not on legitimate manufacture and research. This proposal, unlike one that would focus on the drugs themselves, does not set up a regulatory or administrative framework with which the legitimate industry and researchers would have to comply. It places no additional burdens on anyone legitimately involved with these types of substances. Legitimate activity regarding new drugs is protected by the exemption for manufacturing or distribution of a substance in conformance with the new drug approval provision of the Federal Food, Drug, and

Cosmetic Act. Early-stage clinical research activity is protected by reference to the exemption from the new drug approval requirement for investigational use. Also, nonclinical research and industrial applications would not be affected since they are not "intended for human consumption."

The legislative definition drug provides additional protection for legitimate activity and a clear statement of the focus of the proposal. The term designer drug is defined to mean a substance other than a controlled substance (defined in 21 U.S.C. §802(6)) that has a chemical structure substantially similar to that of a controlled substance in Schedule I or II or that was specifically designed to produce an effect substantially similar to that of a controlled substance in Schedule I or II. The definition also provides examples of chemical classes in which designer drugs are found. The definition requires that there be a substantial degree of similarity in order for a substance to be considered a designer drug. Moreover, if the substance falls within the purview of the definition because of its effect, rather than its chemical structure, the substance must have been specifically designed to produce such an effect. Thus, for example, although caffeine may produce effects which resemble those produced by certain controlled substances, the similarity is not so significant as to bring caffeine within the purview of the definition of designer drug nor would its design meet the "effect" requirements of the definition. This

proposal is not intended to cover alcoholic beverages, tobacco products, aspirin, or other legitimate consumer products and these, too, would not meet the definition.

The proposal also includes technical provisions which clarify the applicability of the new drug approval process of the Food, Drug, and Cosmetic Act and establish a definition for the term "human consumption." For the purposes of the proposed provision, the new drug approval process of the Food, Drug, and Cosmetic Act would apply irrespective of intent to introduce the substance into interstate commerce. Thus, the broad scope of the Controlled Substances Act (which requires no interstate commerce nexus) applies to the proposed exemption, as well as to the proposed offense, in contrast to the Federal Food, Drug, and Cosmetic Act's requirement to show delivery or introduction for delivery into interstate commerce. While this latter requirement may be interpreted broadly, it is not appropriate or necessary for the proposed criminal statute. The term "human consumption" is defined broadly to include application, injection, inhalation, or ingestion.

The approach taken by this bill provides for an effective and, most importantly, an immediate law enforcement response to the manufacture and distribution of designer drugs. No longer will individuals be able to circumvent the Controlled Substances Act through skillful manipulation of the chemical structure of

potent and dangerous drugs. This bill makes manufacturing with the intent to distribute or distributing a designer drug intended for human consumption a crime punishable by imprisonment for up to 15 years and a fine of up to $250,000. This is done without placing additional burdens on legitimate industry and without restricting legitimate research.

CONCLUSION

The designer drug problem is indicative of the increasing complexity and technical nature of the drug abuse and trafficking situation. DEA has responded to this problem using every tool available to it and has, to this point, managed to put forward an effective effort against the most serious of these designer drugs.

We have fully implemented the emergency scheduling provisions of the "Comprehensive Crime Control Act of 1984" and have taken action against the most dangerous and highly abused of these designer drugs. These scheduling actions combined with our continued enforcement efforts are impacting on the traffickers of these dangerous drugs.

However, the nature of this phenomenon is such that the traffickers can and are circumventing our efforts by creating new uncontrolled analogs of controlled drugs. Without additional

legislation, we will continually be one step behind many of these drug traffickers. This is a situation which obviously is not to be tolerated when people are being killed and crippled by unscrupulous individuals who manufacture and distribute designer drugs.

I will like to thank you, Madame Chairman, for calling these hearings to bring even greater attention to this important problem. I will be pleased to respond to any questions you or Members of the Subcommittee may have.

Thank you.

Senator HAWKINS. Thank you. Your full statement will be entered in the record for the benefit of the other members of the subcommittee who are very concerned about this subject.

To your knowledge, Mr. Lawn, is there any significant involvement in synthetic drug trafficking, by organized crime?

Mr. LAWN. No, Madam Chairman. We have no information of traditional organized crime's involvement in the analog situation. But as was referenced here this morning, based upon my many years of experience as a law enforcement officer, if there is considerable proceeds to be made, certainly, organized criminal elements will look into how it can be done.

Senator HAWKINS. You heard earlier witnesses, who were drug addicts, say that in many instances they were served by 8 or 9 year-old kids when they made their purchases. Is there anything in the administration's bill that addresses that?

Mr. LAWN. No, there is nothing addressing that, but again, I do not believe that to be a new phenomenon. Within the past year, there was a major case in the city of Detroit in which children younger than 18 years of age were used in any of a number of capacities so it was not something that was as much of a surprise to me as indeed it was to many other people.

Senator HAWKINS. Yes, well, this happens as well in the District of Columbia. How do you plan on addressing that? As we tighten the penalties, making them more severe and making the fines greater for the manufacturers and the sellers of synthetic drugs, schemes continue to be devised for younger and younger children to be the ones who handle the drug transactions. How do we address that? This is a horrifying reality. It is not a new phenomenon—it is something that has happened over and over again.

Mr. LAWN. I think the strategy is twofold. First is to keep the drugs from ever getting to the middleman, and that would be the role of DEA in dismantling major organizations. Secondarily, I think that an important aspect is education.

Senator HAWKINS. Well, I think we learned much from the film of individuals who had used just one dose of synthetic drugs and were permanently afflicted; affected, as well, by the two gentlemen who had been drug abusers for years. We should take such an educational program on the road, as you and I have discussed before, to junior high schools, as so forth. This could demonstrate the horrors of synthetic drugs to everyone. We could get a lot of organizations to sponsor it, because a picture is worth a thousand words. We all do an awful lot of talking, but I am very concerned about what is happening with these young people who deliver a deadly substance that can be held in the palm of your hand, as the doctors said, that would be death or a crippling lifetime for thousands and thousands of people. And if that little handful can be parceled out to one little dot, as Senator Chiles showed us, we have a big, big problem on our hands. We already had a big problem before this started, and I think we need to tailor the legislative remedy a little to look at reality.

Mr. LAWN. Well, in the case of the designer drugs, as everyone else has stated this morning, I too do not like that particular terminology, but——

Senator HAWKINS. We ought to knock it off, starting today; all our charts say that.

Mr. LAWN. The proposed bill will be very helpful to us because we can then go after the chemist who is manufacturing a different analog. By way of example, DEA recently arrested two chemists in a laboratory—one, a Ph.D., another with some background in chemistry. Our laboratories are currently looking at the substances which were being made. If the substances that were being made are analogs different from a controlled substance, these individuals have not committed a crime.

That is the reason this bill is so very important.

Senator HAWKINS. You heard the testimony of the California witnesses who said that they seemed to feel—and it was reiterated by other panelists—that there is an "evil genius chemist" in California. Is that very difficult to have a dragnet and find that man or woman, or individual?

Mr. LAWN. The difficulty would be the difficulty again that was enunciated this morning, and that is that the chemist could have produced these analogs several years ago and is now just distributing them whenever the mood or whenever the financial crisis creates a situation where they need to be distributed.

We do not believe that there are a great many chemists involved, but in the case that I previously mentioned, it would be a tragedy and indeed, a sorry situation for society, if the two chemists involved in this recent investigation are released because the analogs they are producing are indeed not controlled substances.

It gives a very, very bad message.

Senator HAWKINS. I feel, as a parent who purchased, had to sign for, cough medicine that had been prescribed, and was therefore controlled, that if that kind of registration exists, that the same procedure can exist for the purchasers of equipment for synthetic drugs. That way, we could do the necessary tracing, if we had the national will to do that. If condeine can be traced to housewives, why in the world can't we trace to the origin of the first purchase of the ingredients we know are in synthetic drugs. The basic substances still have to be purchased, do they not?

Mr. LAWN. Yes, ma'am. But most of those chemicals are chemicals used licitly.

Senator HAWKINS. I do not care. I would like to have these purchases registered. If the chemists want to have the materiels, what is the problem with signing a receipt for them? If you would send something by registered mail, it would have to be signed for; it seems to me that the control can be that simple, just to get a handle on where the stuff is going. Chemists who purchase this equipment have nothing to fear if they are doing legtimate business.

Have you all thought about that?

Mr. LAWN. Well, as you know, Madam Chairman, we have a very active chemical control program in the area of ethylether——

Senator HAWKINS. I know that, and I like the way we trace that, by the way.

Mr. LAWN. Thank you, and while the ethylether problem is much easier for us, it is because ethylether is predominantly used in the final process of cocaine hydrochloride. When you are talking

about chemicals used regularly in the licit market, you are talking about a tremendous drain of people power in investigating people who legally have a need for these chemicals.

Senator HAWKINS. Well, we will pursue that further in a private conversation.

Senator Grassley has joined us. I am always happy to have him participate in our hearings, and his interest in this panel is most appreciated by this chairman.

Welcome. We have had very interesting testimony and a powerful film which we will provide to you to see at your leisure.

Senator GRASSLEY. Thank you

I would like to ask about heroin. Designer drugs are, I hope, not a problem in my State. I don't think they are, but I suppose if it is a new problem, it will be going there. But we do have a terribly high heroin usage rate in my State of Iowa. I would like to ask, if one chemist could produce the world's heroin, how come that has not happened yet?

Mr. LAWN. I am sorry, Senator. I do not understand the question.

Senator GRASSLEY. If one chemist could produce the world's heroin, why hasn't that happened yet—if we have the development of designer drugs in other areas.

Senator HAWKINS. It is on its way.

Mr. LAWN. Synthetic heroin is produced regularly in the United States and elsewhere throughout the world.

Senator GRASSLEY. It is?

Mr. LAWN. Yes, sir.

Senator GRASSLEY. Well, then, why isn't the synthetic heroin a bigger problem today than it is, compared to some of the other designer drug problems?

Mr. LAWN. I would say that the basic reason would be because of the availability of heroin throughout the world. Heroin is not scarce throughout the world. Perhaps, if there were a paucity of heroin, we would see more synthetic heroin.

Senator GRASSLEY. Well, is it not true that designer drugs sell cheaper on the market than the real stuff, and then wouldn't there be a market orientation toward the synthetic heroin?

Mr. LAWN. As we heard this morning, about 70 percent of the users of designer drugs in California actually believed that they were purchasing heroin and did not know they were puichasing a synthetic analog.

Senator GRASSLEY. So, then, the marketplace is not operating.

Mr. LAWN. Well, the marketplace is operating——

Senator GRASSLEY. I mean not in a sense that distinguishes between the two, as far as prices.

Mr. LAWN. No, sir, not in the sense of distinguishing between the two.

Senator GRASSLEY. OK. How many designer drug labs have been uncovered?

Mr. LAWN. Several. Let me turn, please, to Mr. Buzzeo.

Mr. BUZZEO. Yes, Senator. In June of 1985, two labs in California were closed and two chemists were arrested.

At this point in time, we do not know if the analogs that were manufactured are controlled or not. It is possible that they are one of the analogs of fentanyl that is not a controlled substance.

And in Texas, near the border, a lab that was being transferred from California to Mexico was seized. The material also was seized.

So it is three labs in the past year.

Senator GRASSLEY. Thank you.

Madam Chairman, I have no further questions.

Senator HAWKINS. Thank you.

Senator Dodd?

Senator DODD. Thank you, Madam Chairman. Just a couple of questions.

Mr. Lawn, the record of that March 13 hearing when I raised the question, without asking for a response, but that you just submit in writing what the agency was doing, I presume it would be all right if I take your testimony today so they can complete that record, and this will be the response of the DEA to that question on March 13?

Mr. LAWN. I am sorry, Senator. I recall the hearing, but I do not recall our receiving any question concerning what we are doing in the designer drug area.

Senator DODD. Well, if you would like, I will get you a copy of the transcript. The clerk has notified us that the transcript is still open; that is the problem.

Mr. LAWN. Well, I do apologize, Senator.

Senator DODD. Well, I am sure it wasn't intentional; I am sure it was unintentional.

Mr. LAWN. Well, thank you, Senator. I will get a response to you immediately.

Senator DODD. I appreciate it, and I would like your help. Along the same lines as the chairman, I would like to get your assistance and help. My intention would be with the legislation that is coming along to offer language to that legislation which would provide some substantial penalties to people who recruit children, infants, in the marketing of drugs. It would be helpful if we could get some guidance from your staff as to the drafting of such an amendment and language. And I presume there would be no objection to that, because it is a new element, it seems to me; it is not something that has happened in the last month or two, but relatively new, the recruiting of children at the elementary school level to act as runners is relatively new, to avoid prosecution.

Mr. LAWN. Yes, sir. We would be pleased to work with your staff.

Senator DODD. I would appreciate that very much.

The problem I mentioned earlier—and I am sure you heard me raise this with William—about that middle person—I am embarrassed to tell you, in an affluent State like my own in Connecticut—and we are a very affluent State; we have surpluses in our budget, and the towns are relatively affluent in the State—we have exceptions, but what small amounts of money are allocated by our communities for the purchasing and so forth that you need to do in order to make your arrests and have successful convictions are just not adequate enough to get at that middle person. They get budgets of like $2,500 or $5,000 a year for the buys. And you may have heard me say that at least the police that I deal with in Connecticut State—and I think with some degree of accuracy and justification—that you cannot take resources you have and get at that middle guy. You are really more interested in that supplier.

Do you have any ideas, aside from trying to awaken community and State awareness to allocating some additional funds so that they can actually start making purchases, not from runners, but to get into that middle category—what are your thoughts on that? First of all, is that accurate? I should ask you that first of all.

Mr. LAWN. Senator, it is accurate. I would say that in recent years, the Drug Enforcement Administration has a program to get at the midlevel individuals, and these are our State and local task forces. Currently, we have 26 funded State and local task forces where the State and local officers work with DEA personnel; DEA will supply the equipment, the overtime pay, and these task forces have been most effective. We have an additional 25 informal task forces, and these are task forces in which there is a need, but there is no funding to support that need. We do it on an informal basis nonetheless.

The conviction rate for these task forces throughout the country is about 90 percent, and it is the midlevel trafficker, and it is a most effective program. It is a program that takes not too many agents from the international effort, and it is a focus that we, like you, think is very important.

Senator DODD. Isn't it really hard, though—you have really got to get people on the inside. These guys do not sell to anybody. And this was not an infant who came out and sold that half-gram of cocaine to me; it was an adult. And he is on film now. Apparently, a number of times he has sold, so they are building up a pretty good case on this guy, and at some point, will spring the whole thing. But the fellow that he got the stuff from inside that building, he does not sell to anybody; he knows exactly who he is selling to.

And one of the problems that some of your people, not to me directly, but again to undercover operations in Connecticut, identified is getting people on the inside. First of all, it is a risky, risky business. Are we doing enough to assist you in that arena—the resources, so that you can recruit or pay for that informant, that paid informant, that undercover operative who puts his life on the line by going in and developing a relationship so that you actually get a crack at that middle guy?

Mr. LAWN. To respond to that question is the Congress doing enough, this Congress has done much for drug law enforcement. In 1974, the Drug Enforcement Administration had 2,200 agents. In 1984, we finally returned to that same complement of 2,200 agents, and we have been building from the losses we sustained in the seventies—and incidentally, the losses sustained on the Federal level parallel the losses in law enforcement on the State and local level as well. This Congress provided the Comprehensive Crime Control Act which has been most effective. If this designer drug bill is passed, it will be most effective in minimizing this designer drug problem before it becomes a substantial problem.

I think that what is happening here in Congress has been most supportive of drug law enforcement initiatives.

Senator DODD. Well, I appreciate your saying that, and presume there is a point at which your ability to handle additional resources is an administrative problem as well. But getting back to the 1974 level, the problem is substantially different than it was 12 years ago—I presume, growing—because you are talking about

2,200 people in 1985-86 is not, I presume, adequate enough in terms of what you can deal with at this particular juncture, but I presume we are going to need to do more.

Mr. LAWN. I have told various committees, Senator, that certainly, we are satisfied with the budget that we have received, but the budget that we have received and the personnel that we have so graciously received to enable us to reach that complement are not in the long term going to be able to do the job for us. We will need over the next few years more resources.

Senator HAWKINS. Sure. You won't turn them down if we fight for them, will you?

Mr. LAWN. No, Madam Chairman, I certainly won't.

Senator DODD. There are agencies out there where they are a bottomless pit; I mean, they will never turn down anything. We are not asking you to do that.

Let me also ask you—and I do not know if it is in the bill or not, and it may be in the bill, and if it is, then disregard the question—but apparently, one of the earlier witnesses mentioned that there are really only two labs in the country, one of which DEA has, in terms of the protection.

I just finished reading this article that appeared in Science magazine of March 1985, which is a whole piece on designer drugs, and the tremendous difficulty in detecting designer drugs; it is really not an easy matter.

Do we provide for additional funds for increasing the number of labs? As I read this article, it seems to me like that is something we could do in a meaningful way that would be helpful to confront this particular problem. Am I missing a point in this?

Mr. LAWN. No, sir. In point of fact, it was the DEA laboratory system that identified the analog problem initially. And as far as resources, in our current request, we have asked for what we believe to be a sorely needed commodity, additional chemists and additional equipment for these laboratories. So our budget request does include those items.

Senator DODD. But that is to deal with the present number of labs, which I understand is two. The question I have is do we need more labs in addition to more equipment.

Mr. LAWN. Let me turn to our chemist, who would be in a better position to answer that.

Mr. SAPIENZA. One of the problems is identifying materials in solid dose form that are out on the street. The DEA lab system can do that very well. Once these analogs are initially characterized, probably many of the other labs at the State and local level could also do that.

The other problem, though, is identifying these analogs in body fluids—that is, people that have used these analogs, and come into the hospitals. At the present time, there is the one lab in California that is routinely doing that. Other labs may be able to do that if they know what they are looking for. I think the problem lies for the most part in knowing which of these analogs are available in which parts of the country and in which cities.

Senator DODD. That is more information sharing, then, rather than additional labs.

Mr. SAPIENZA. Yes. I think as the designer drug phenomenon becomes more publicized and as the forensic community starts sharing information more, that more of the labs will be able to identify these designer drugs. That is not to say that it does not need better tests or more efficient tests; certainly, more could be done in that respect, as well.

Senator DODD. OK. Well, again, I thank you for your testimony this morning. I wish we had some immediate answers, and I am sure you do as well. I see your predecessor every now and then around the streets of Connecticut, Bud Mullen.

Thank you for being here.

Senator HAWKINS. Thank you for your participation in this hearing. Your expertise is always appreciated by this Senator and by this committee. I think the American public will agree with the assessment that something has to be done to stop these high-tech killers. It is going to be an epidemic, and we would like to intervene before more people take that first dose of a bad batch. So, we appreciate working with you, Mr. Lawn, and your skilled staff. I am sure that by working together, the combined efforts of law enforcement, the medical community, chemical manufacturing industry, the administration and this body, we can solve this problem.

Thank you very much.

Mr. LAWN. Thank you.

Senator HAWKINS. This hearing is adjourned.

[Whereupon, at 12:20 p. m., the Subcommittee was adjourned.].

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